ORIGINAL

IN THE DISTRICT COURT

FOR THE DISTRICT OF NEW JERSEY

ANTONIO CIPOLLONE, individually and as executor of the Estate of Rose D. Cipollone,

Plaintiff,

-against-

LIGGETT GROUP, INC., a Delaware corporation, PHILIP MORRIS, INCORPORATED, a Virginia corporation and LOEW'S THEATRES, INC., a New York corporation,

Defendants.

Civil Action No. 83-2864 (SA)

Deposition of ANDREW SIVAK, a witness, taken by plaintiff pursuant to agreement, at the offices of Messrs. Webster & Sheffield, 237 Park Avenue, New York, N. Y. 10017, February 28, 1991, at 11:15 a.m., before Jose A. Centeno, a Certified Shorthand Reporter and Notary Public of the State of New York.

APPEARANCES:

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ALSO PRESENT:

MICHELLE BROWN

oOo

(Curriculum vitae marked Sivak Exhibit 1 for identification as of this date.)

(List of publications marked Sivak Exhibit 2 for identification as of this date.)

(Whereupon, a conference call was held with Hon. Robert Hedges.)

THE MAGISTRATE: Good morning. Do you have the stenographer?

MR. KEARNEY: We have the stenographer.

THE MAGISTRATE: For purposes of the record, I spoke with counsel before the stenographer was available. I understand Mr. Kearney is concerned by the presence of Dr. Harris at the deposition this morning.

Mr. Kearney's position is Dr. Harris, according to Mr. Edell, had insufficient time or no time given his schedule to submit himself for the deposition Mr. Kearney wanted. And now that Dr. Harris is here this morning, Mr. Kearney wants certain relief including an order barring Dr. Harris from the deposition and requiring Dr. Harris to make himself available for the

deposition.

Mr. Edell's response, I take it, is that Mr. Kearney himself is guilty of some discovery violations or some discovery abuse because of late production of an expert's report, that Dr. Harris coincidentally was in New York today for a business meeting commencing at noon, and Dr. Harris agreed to make himself available for an hour and a half to Mr. Edell so Mr. Edell could better take the deposition that is supposed to be taking place.

Is my summation of your position accurate, Mr. Kearney?

MR. KEARNEY: Your summation of my position is accurate.

THE MAGISTRATE: Mr. Edell, is that correct as to you?

MR. EDELL: With one exception, your Honor. When this matter was first before you, we dealt with Dr. Harris' availability, I believe, up through the beginning of January. And we indicated at that time that he was unavailable. Subsequent to that point in time, as consistent with the position taken before

Judge Sarokin, I advised the court that although we could probably eke out the time for a day of deposition, that Dr. Harris had just reached the point where he no longer wanted to go through the harassment that he had experienced for the 20 some odd days that he had already experienced in the deposition process. And that was made clear to Judge Sarokin during the hearing we had before Judge Sarokin.

So with that exception, your Honor, you accurately described my position.

MR. KEARNEY: May I make a point before you rule, Judge, a point of information?

THE COURT: Go ahead.

MR. KEARNEY: Before I placed the call, I asked Mr. Edell if he intended to have Dr . Harris to sit here for this entire day of deposition. His answer was yes. I asked him if he intended to have Dr. Harris sit for the deposition tomorrow. His answer was probably not tomorrow. If there is an issue of fact here I propose we put Dr. Harris under oath right now.

THE MAGISTRATE: No, I don't think I can make an appropriate determination of credibility over the telephone.

MR. KEARNEY: And one other thing, Judge, let me conclude with this: That, Judge, you looked at this in December and determined that on his Cancer Clock testimony, which is the only thing we are talking about now, that the defendant had inadequate prior notice or opportunity to depose him. And you said that he should stand for a day for deposition. That was part of your order that was appealed to Judge Sarokin.

I have Judge Sarokin's ruling in front of me. Judge Sarokin said he would not take a position on that one way or another, he would not rule whether or not the defendants had prior opportunity to take deposition. He held that in abeyance and said to Mr. Edell, "Can't you get him to come down for deposition?"

Mr. Edell said he would inquire. The thrust is your order has not been overturned, and the finding based on that, the

defendants did not have an opportunity to take Mr. Harris' deposition on Cancer Clock. It seems clear that in essence what the plaintiff has said to you and Judge Sarokin is that Dr. Harris is unwilling to attend a deposition in the Cipollone case. He is unwilling to subject himself to that.

I would submit that implicit in that was that Dr. Harris had other commitments that would preclude him from doing that. What is clear now from his presence at this deposition is that Dr. Harris has the time, has the inclination to appear in New York to attend somebody else's deposition on this same subject, and that certainly should be taken into account in your rulings on whether or not he should be standing for deposition. It simply boggles the mind that with everything that was said to you and Judge Sarokin that Dr. Harris can come in here with what I understood with what Mr. Edell said to me was the intention of being here all day for somebody else's deposition on the subject when he has adamantly refused to stand for his own

deposition on the subject.

MR. EDELL: So the record is clear, in the event this thing has to go any further, the representation that I made to Mr. Kearney this morning was, when he asked me "Is Dr. Harris going to sit in on the deposition?" I said "Yes." He said, "Is he going to be here tomorrow?" I said, "No, probably not."

With respect to his availability today to sit in on the deposition because of the fact that on Monday, February 25th at 7:29 p.m. I was first faxed the seven page summary and report of the witness who was to testify here today together with the references attached to the report.

Your Honor had a conference call with Miss Walters in my office yesterday. As a result of that tardy furnishing of that report, which the defendants, Mr. Kearney's office, specifically had in their possession shortly after October 31, 1990, which is the date of the cover letter from the witness to Mr. Decker of Mr. Kearney's office which has been marked as Sivak 7 -- the report has been marked as

Sivak 4 -- they had that in their possession prior to furnishing us with the one-page 1990 summary marked as Sivak 3.

I had asked Dr. Harris whether or not he could help me under the time constraints that we now were placed under to take this deposition, in light of the fact that we had other depositions scheduled for the remainder of this month, that we have been given the mandate by Judge Sarokin that we have a trial date of April 1st.

Dr. Harris indicated to me that he had to come to New York today to attend a meeting which is unrelated to this litigation, but said he might be able to afford me an hour to an hour and a half. In fact, he arrived here at 10:00 a.m. and has to leave 11:30 a.m. So he will not even be able to sit here or help me in the course of this deposition.

As I indicated previously, Dr. Harris indicated when this matter first came up, as I indicated correcting your Honor's summary of the position, that he would not be available for the deposition. But that

position was changed -- not changed -- but my representation to Judge Sarokin after the beginning of January was that the witness, Dr. Harris, no longer wanted to go through the harassment which he was exposed to. And the penalty that Judge Sarokin imposed upon me was my inability to use any of the supplemental opinions expressed by Dr. Harris in the supplemental report.

And that is the sanction that he imposed for our failure to be in a position to produce Dr. Harris for further deposition. And that was the upshot of the appeal from your Honor's prior ruling.

THE MAGISTRATE: All right, gentlemen, I've heard enough.

MR. EDELL: These were marked previously. I'm going to ask the court reporter to mark them and append them to this portion of the transcript so it is a complete record.

MR. EDELL: The documents supplied to the court yesterday, I refer to Sivak 3, Sivak 7, and Sivak 4.

MR. KEARNEY: Your Honor, I must respond.

THE MAGISTRATE: There is no need to respond to it now, Mr. Kearney. I'm prepared to make a ruling.

MR. KEARNEY: I make a request to respond to Mr. Edell's statements respecting Sivak Exhibit marked 3, 7, and 4.

THE MAGISTRATE: There is no need. I'm satisfied that argument is irrelevant. I'm not prepared to take it into consideration.

Now, gentlemen, it is now by my watch 11:30. Dr. Harris may leave the deposition, and he is to leave the deposition now. I choose not to issue any further ruling in this regard until I've seen the transcript. I'll ask you, Mr. Kearney, to make sure I get that portion of the transcript, including your argument and my comments, as well as these exhibits, just so I can see them for purposes of the record. After I see that I'll decide what further action, if any, I want to take in this regard. Thank you, gentlemen.

MR. KEARNEY: Thank you, Judge.

MR. EDELL: Thank you, Judge.

Will you mark these, please.

(Report of Andrew Sivak marked Sivak Exhibit 3 for identification as of this date.)

(Letter dated October 31, 1990 marked Sivak Exhibit 7 for identification as of this date.)

(Report entitled "The Cancer Clock" initialed Sivak marked Sivak Exhibit 4 for identification as of this date.)

A N D R E W S I V A K, called as a witness by plaintiff, being first duly sworn by the Notary Public (Jose A. Centeno), testified as follows:

EXAMINATION BY MR. EDELL:

Q. Please state your name and address for the record.

A. Andrew Sivak, [DELETED]

Q. Dr. Sivak.

A. Yes.

MR. EDELL: I'm Marc Edell. We introduced ourselves before we started here. I'm an attorney. I represent the plaintiff in this case.

Have you ever been deposed before,

sir?

THE WITNESS: No, I haven't.

MR. EDELL: Have you spoken to Mr. Kearney or Mr. Decker concerning the nature of a deposition?

THE WITNESS: Yes, they have told me.

MR. EDELL: They gave you the general guidelines?

THE WITNESS: Yes, sir.

MR. EDELL: They told you you are not to guess. You are to give us factual information in response to a question?

THE WITNESS: That's right.

MR. EDELL: If any of my questions are unclear, you don't understand them, you should tell me that and I'll try to make them make sense or clarify my question.

THE WITNESS: I understand that.

MR. EDELL: If at any point in time Mr. Kearney or anyone else in this room has an objection, please hold your response until they've had an opportunity to place their objection on the record, at which time Mr.

Kearney will tell you you should answer or not answer your particular question.

THE WITNESS: That's right.

MR. EDELL: The gentleman to your right is a certified shorthand reporter. He can take down anything you can say, but it's difficult for him to take nods of the head or gestures, so all your responses must be audible.

THE WITNESS: I understand.

MR. EDELL: If at any time you wish to take a look at a document or take a break for any purpose, please feel free to do so.

THE WITNESS: Okay.

MR. EDELL: If at any juncture you have a question of Mr. Kearney, or me, or Mr. Decker, you can turn to Mr. Kearney, or Mr. Decker, or me, and I'll be happy to respond to your question.

THE WITNESS: Okay.

Q. Mr. Sivak, instead of jumping into our Cancer Clock discussion, which I intended to do previously, we'll start from the very beginning as is tradition in this sort of thing. I'm going to show

you a document which we marked Sivak 1.

MR. EDELL: Just to facilitate things, I've premarked all of these I intend to use. At the end I'll give them all to the court reporter. He'll initial them and put the date so we don't have to keep interrupting.

Is that okay with you?

MR. KEARNEY: That's okay.

MR. EDELL: I have three copies, I have copies for three people.

Q. I show you Sivak 1. Have you seen this document before, sir?

A. I prepared it.

Q. You prepared this document?

A. Yes.

MR. KEARNEY: Could we go off the record.

(Discussion off the record.)

Q. You prepared the document which we have marked Sivak 1?

A. That is correct.

Q. When did you prepare it?

A. About a year ago.

Q. For what purpose?

A. In addition to my position as head of Health Effects Institute I do consulting in environmental health related issues outside of that. And people asked for a CV if they want to use my services, and I prepared that for that reason.

Q. Let's go through this together. Let's see if we can get the chronology correct. What is your date of birth?

A. May 31, 1931.

Q. You graduated from Rutgers in 1952, undergraduate?

A. With a bachelor's degree.

Q. Bachelor of science?

A. Bachelor of science and biology.

Q. You immediately went for your master's degree?

A. No, I went into the navy.

Q. And how long were you in the navy?

A. Three years.

Q. Where were you stationed?

A. I was on board a capital ship, a cruiser.

Q. Where?

A. In the Atlantic fleet until the very last six months when I took the ship to the Pacific fleet.

Q. You got back 1955?

A. December '55 I was discharged.

Q. It was an honorable discharge?

A. Yes, it was, and I was offered a premature advance in rating.

Q. After you got out of the navy, what did you do?

A. For nine months I worked at E.R. Swift & Sons in their medical library doing medical abstracting as I was thinking what I wanted to do with the rest of my life.

Q. Then what did you do?

A. Went to graduate school.

Q. At Rutgers?

A. Rutgers University.

Q. For your master's?

A. Got my master's degree in 1957.

Q. What was your master's degree in?

A. Microbiology and microchemistry.

Q. You continued at Rutgers to get your doctorate degree?

A. That is correct.

Q. Did you work anywhere during this period of time?

A. No. Full-time graduate student.

Q. You got your Ph.D. in 1960?

A. That is correct.

Q. In what?

A. In microbiology and microchemistry. That was at the Watsman Institute.

Q. What was your thesis?

A. Looking at the biochemistry, how an antibiotic is synthesized by the microorganism that makes it.

Q. Did you do any laboratory research or experiment with respect for that thesis?

A. I did it all.

Q. Were these animal studies that you performed?

A. No. It was mostly biochemistry.

Q. After you got your Ph.D. in 1960 what did you do?

A. Took a one-year postdoctoral fellowship in the University of Vienna in Austria.

Q. What did you study?

A. Also a microbiochemistry project.

Q. You came back in 1961?

A. That is correct.

Q. What did you do then?

A. I then went to Arthur D. Little in the Life Sciences Group at the time.

Q. What was your position at the Life Sciences Group?

A. I was a staff scientist.

Q. What were your responsibilities?

A. Almost all of my effort for the two years that I was at ADL was, at that juncture, was related to studying anticancer drugs, looking at how to measure a new class of drugs that was just going into the clinic, devising methodology so we could determine those in the tissues and blood samples of patients, and doing animal experiments in dogs and rats to sort of get the data before we went on to humans.

Q. Who were you doing that research for?

A. National Cancer Institute.

Q. Who else was working on that project?

A. Well, it was part of a very large team. Arthur D. Little had a major segment of National Cancer Institute work at the time. The chief project officer was Dr. Charles Kensler. My immediate superior was Dr. William Rogers.

Q. Who else did you work with at Arthur D.

Little on this project?

A. It's almost 30 years ago.

MR. KEARNEY: Take your time.

A. Dr. Philip Thayer, Dr. Paul Palm, Irene York. I just don't remember who some of the technicians were that worked in the lab. But the key person I worked with was William Rogers. He and I were sort of a team in the biochem lab that worked together.

Q. Is Dr. Rogers alive today?

A. Yes.

Q. Where is he located?

A. In Massachusetts.

Q. Do you know where he works?

A. He's retired from Arthur D. Little and a private consultant right now.

Q. Do you know where he lives?

A. Yes.

Q. Where?

A. I don't know his exact address but he lives in [DELETED]

Q. Irene York?

A. I don't know where Irene is. Irene was sort of my right hand in the laboratory. She and I

worked together devising the things. I don't know where she is. I think she's married. I don't know where she's gone to.

Q. Specifically with respect to these anticancer drugs, tell us exactly what you would do? Did you design the study to see whether they were effective? Did you conduct laboratory research to see what effect they had on human tissue, or all of the above?

MR. KEARNEY: Let me interrupt a minute. I'm going to reiterate one of Mr. Edell's instructions, and that is give me time to interpose an objection please before you answer the question.

I object to the form of that question, but you can answer the question.

A. As I indicated earlier, the Arthur D. Little project was an extremely complex one, in fact covering all if the issues that you raised from effectiveness all the way through. My particular piece of it was looking at how one measures this particular drug in a body fluid or a tissue. And, yes, I designed the experiments. And, yes, I carried them out with my own hands. And, yes, I wrote the

reports that ultimately went to the National Cancer Institute on my piece of the research.

Q. Let me see if I understand it. Your slice of this whole project was to devise a mechanism by which you could measure the particular drug by making assessments of body fluids or body tissue?

A. That is correct. And the tool primarily was biochemistry. That was the discipline one needed to apply to this.

Q. Your slice didn't have anything to do with whether the drug was or was not effective in curing cancer or preventing cancer?

A. No. That was done by another piece. And the reason, of course, we looked at the drug is that in test animal systems it had been shown to be effective, so it had moved fairly well along the National Cancer Institute pipeline.

Q. But you didn't have any responsibility for that particular area?

A. Only in the matter of trying to understand how the drug worked. One thing, there was an interesting wrinkle that fell out of our work, that we found that the material bound to DNA. And we thought that that might be the mechanism for how in

fact it cured the cancer. So that little piece of work that came out of my work did relate back to why and how this drug might work as an anticancer drug.

Q. Is that basically what you did from '61 to '63, work on this particular project?

A. That was the great majority of it. There were a few other very small things I participated in, but that was almost all of my effort.

Q. On any of those smaller projects did they have anything to do with Ligget & Meyers?

A. No, they did not.

Q. Were you aware at that time that Arthur D. Little had been doing work for a number of years for Ligget & Meyers?

A. Yes.

Q. How did you know that?

A. We had staff meetings every Tuesday afternoon, and the entire research projects of the Life Sciences Group were reviewed by the staff.

Q. So even if you weren't working on a particular project, you would be apprised of how the other projects were progressing?

A. No. We knew that they were going on. The specific details of how the projects were going

were not related at those staff meetings.

Q. And who would chair these staff meetings?

A. Kensler.

Q. Were there meeting minutes kept of these staff meetings?

A. I don't think so.

Q. You never saw them?

A. I never saw them. The purpose of the meetings was to lay on the table things where we could help each other or where there were logistic problems, instruments needed to be cared for, really housekeeping to keep the place going.

Q. What was your understanding of the work that Arthur D. Little had done for Ligget & Meyers? We're talking in 1961 to 1963. What was your understanding at that time?

A. My knowledge, and, again, because the laboratories were sort of cheek by jowl, there were cigarettes that were being smoked to collect cigarette smoke condensate, and those condensates were tested for carcinogency on the backs of mice.

That's all I know about what was going on.

Q. Do you know who at the Life Sciences

project worked for that particular project for Ligget & Meyers?

A. The two names that come to mind are Philip Thayer and the guy that sort of ran the day to day, Eugene McSweeney.

Q. Do you know where he is today?

A. I haven't seen or heard from him in 15 years.

Q. During that period of time did you have any teaching positions?

A. Not at that time.

Q. Were you writing any articles?

A. Yes, there were a number of papers that were published as a result of that work on this drug during those two years.

Q. Did you write on any other particular topics other than the work you were during at Arthur D. Little during 1961 to 1963?

A. Not in that interval of time.

Q. Were you taking any particular courses at that time, any school or any continuing education?

A. I don't recall any.

Q. 1963 you left Arthur D. Little to go where?

A. I went for one year with a former friend of mine in graduate school, starting a toxicology laboratory by the name of Biodynamics located in East Millstone, New Jersey.

Q. What type of work did this organization do?

A. This was primarily a toxicology testing laboratory.

Q. Why don't you explain to us toxicology, what is toxicology?

A. For a variety of chemical consumer products and drug companies we were doing testing in animals looking for the potential hazards of exposure to these to obtain ultimately for drugs Food and Drug Administration clearance for those drugs and consumer products to assure the clients that we had, that in fact if they entered their products into the marketplace that, for example, a cosmetic that skin or eye damage would not occur.

Q. Who were the clients you worked for for this one year period of time?

A. There was an agreement that I had with them with respect to who the clients were and what we did, and I don't think I'm free to disclose that.

Q. So you were not free to disclose who the clients were?

A. That is correct.

Q. And you believe that that is still -- the work you did for the one year from 1963, '64 would still remain confidential, should still remain confidential?

A. My recollection is the confidentiality agreement had no outside term, and I would assume I am still covered by it.

Q. Whoever these companies were they came to you and they said "We want to market this particular product," would you test it for its toxicity, is that what you do?

MR. KEARNEY: Objection to the form of the question. You can answer the question.

A. Most of our studies were done very early in the product line development. Before anyone would really make a marketing decision, it was pretty much after the chemist or somebody had found something. And our particular role was to provide for our clients biological information on the effects of these materials in systems that we were testing.

Q. And the systems you were testing were

animal systems?

A. That is correct.

Q. What types of animals were you using?

A. They ranged all the way from mice to monkeys.

Q. How would you determine what particular animal system to use?

A. For things that were related to government clearance. For example, like pesticides and drug and food additives, there is government documentation that lays out this is the kind of test you are going to run, this number of animals, and these are the things you look for. And by and large most of it was regulatory driven.

Q. For example, did you do any biological testing with respect to the potential carcinogenicity of any of those products?

A. Not while I was there. Most of the things that I was doing or involved in there were relatively short-term things. I think a three month's study was the longest one during that time I was there.

Q. Was there testing with respect to carcinogenicity that you can recall?

A. Not while I was there.

Q. Would you give us the name of the classmate?

A. Yes, Thomas Russell.

Q. Is he still around?

A. Yes.

Q. Where?

A. It's a remarkable story and I wonder whether I should have stayed there. I would be a far wealthier man than I am.

Q. But would you be happier?

A. That's the question. Tom is the chairman of a board of now a set of companies that include Biodynamics and about four or five other companies he and a group of people acquired. But he's still around and can be reached through Biodynamics in Millstone, New Jersey.

Q. You left in '64?

A. That's right.

Q. Where did you go next?

A. Institute of Environmental Medicine, New York University Medical Center, and I was on the faculty there for 10 years.

Q. To get back to your work at Biodynamics,

had you had any training up to that point in time in terms of toxicology?

A. When I was at ADL the first time around when we were doing these measurements of drugs in body fluids, say, of dogs and rats, part of that was in association with the toxicological studies that were being done. So we were part of the team. And, again, I was part of the team that looked at the animals after they were treated when I took my samples off to run it. So I had some hands-on experience at toxicology at Arthur D. Little.

Q. But up that time you didn't have any specific training with respect to toxicology.

MR. KEARNEY: Object to the form.

Q. Formal training, did you have any formal training?

A. Well, at that vintage time the discipline of toxicology was not being taught as such. Most people came into toxicology from biochemistry, from physiology or pharmacology. And toxicology was really learned more by apprenticeship than by a formal academic course training.

Q. Up to the time period 1963, toxicology was not a formal discipline one could take while in

graduate school?

A. That's true.

Q. One would be forced to take a biochemistry type of course or physiology?

A. Some related type of course. And, again, at that time within pharmacology courses there were courses taught related to toxicology.

Q. What did you do when you went to NYU?

A. I joined a group that was interested in chemical carcinogenisis led by Benjamin Van Duuren. My first association with them was a job with the National Cancer Institute to examine the carcinogenicity of cigarette smoke condensate and extract of tobacco leaf.

Q. Chemical carcinogenesis, what is that?

A. The study of how, and why chemicals give rise to tumors.

Q. Had you had any specific training in chemical carcinogenesis prior to going with NYU in 1964?

A. No.

Q. Did you receive any formal training at NYU with respect to carcinogenesis?

MR. KEARNEY: I object to the form

of the question.

A. Yes. There were a couple of instances. One is that I was given a pretty good exposure and sort of a private tutorial in human and animal tumor pathology. It turns out that the then chairman of pathology department, who was very interested in the work that I was doing, thought it would be very good for somebody who was in cell biology to learn how the real world was like. So since I was also a member of the pathology department, he spent some time with me, took me through the works, and taught me a little human pathology.

Q. Who was this?

A. Marvin Kushner.

Q. Did you do any pathology?

A. No.

Q. You didn't actually do any --

A. Well, in order to do pathology formally, you would have to be an M.D. and a board certified pathologist. I was neither.

Q. What is your understanding of what pathology is?

A. Pathology is the examination of tissues to make judgments in the one case about cause of

death, and in surgical pathology you determination, for example, if a tumor is malignant and requires removal.

Q. What was your opinion of Dr. Kushner in terms of his experience and expertise as a pathologist?

A. Probably one of the best in the world ever.

Q. Did you ever change that opinion?

A. Never.

Q. So you learned about tumor pathology from Dr. Kushner. What other formal training did you receive in respect to carcinogenesis?

A. Again, the training in carcinogenesis was actually doing it. The group I was in was largely a group of chemists. I was the senior biologist. And the management, evaluation, writing of that part of our reports that related to the biological section of the carcinogenicity that we were doing was my responsibility.

Q. But you didn't receive any formal training, you didn't take any courses at NYU, did you?

A. No.

Q. Did you take any formal courses anywhere

else in carcinogenesis?

A. There were workshops one would go to. There were groups of people who would gather together to talk about specific issues in carcinogenicity, and I attended and participated in those.

Q. When you say workshops, those are more like continuing education courses?

A. Yes. Groups of people who gather in the same area and shared observations and tried to improve the technology as we were pursuing it.

Q. Did you start taking those workshops when you went down to NYU?

A. Yes.

Q. Can you give us an example of some of the people who taught these types of workshops?

A. They were not so much taught as they were collective sharing of information.

Q. Were they formal workshops or was it just the people who were working at NYU got together and discussed?

A. They were formal workshops and they often occurred at meetings of the American Association for Cancer Research, and there was a small group of people who were doing research on tumor promotion.

Q. Who were these people?

A. Ross Boutwell, Dietrich Hoffman, Thomas Slagg, Fred Boch, a small group of people at that time. That was before that type of discipline really took off.

Q. When you say "that type of discipline" what are you talking about?

A. The study of tumor promotion as a discipline.

Q. Carcinogenesis, is that what we are talking about.

MR. KEARNEY: Objection to the form of the question.

A. We're talking about a piece of the total umbrella of the carcinogenesis. Tumor promotion is one of the experimental pieces of the pie in that broad umbrella.

Q. What was your opinion of the individuals who you named who were teaching people with respect to tumor promotion at that time?

A. They were all competent investigators. We were all sort of peers working on pieces of that problem.

Q. How did you go about determining whether

or not a chemical would cause or could cause tumors?

A. In our particular situation we had several -- the diagnosis and how one went about that depended a little bit on the kind of question you posed. We used mouse skin systems very much for a whole variety of different kinds of chemicals. And of the kinds of studies the simplest would be to apply chemical to the back of a mouse a couple of times a week for the lifetime of the mouse. And as the mouse grew older, one would count the number of tumor, measure them. And at the end of the experiment, we would do a pathology on the tumors. If the solvent gave no tumors and the chemical we tested would give tumors that would be evidence of carcinogenicity on that system.

Q. Why did you use mice?

A. It's a very facile system. It is the only bio-assay system where you can follow what is happening to the tumor as they go along. It's on the surface. You can count them, you can measure them. And the system has been used by other investigators for many years before, and it was well worked out.

Q. When you say the system was used by other investigators for many years, could you give us an

approximation in terms of when the mouse was used as a system to test chemical carcinogenesis first?

A. It probably dates back some 80 years. I think there were some Japanese investigators in the '20s perhaps or even the late teens that reported applying chemicals to the backs of mice and getting tumors. So it's been known almost for the entire history of chemical carcinogenicity.

Q. When was it determined to be a well accepted system as a way of testing for chemical carcinogenesis?

A. I think by the time the early to mid-'50s came that people were then using it for as a fair standard bio-assay.

Q. When you say bio-assay we're talking about a biological system?

A. A biological system to measure carcinogenesis.

Q. Were there any other animals used to test chemical carcinogenesis?

A. Yes.

Q. What animals were those?

A. Primarily rats. But guinea pigs and hamsters were also used.

Q. Why is that?

A. Mice and rats are sort of the currency of toxicologist. They're easy to breed, they are inexpensive, you can breed families closely related to each other. You get genetic information about them so you can understand what your responses are. And guinea pigs and hamsters are looking at alternatives to see if there were differences among species and strengths in animals.

Q. Why were people conducting chemical carcinogenesis studies?

MR. KEARNEY: Object to the form of the question.

A. I think it's primarily from occupational histories people had understood that when workers were exposed to certain levels -- high levels of chemicals, that they suffered an increased incidence of cancer. The most famous is aromatic amines and bladder cancer in England first noted around the '20s and '30s. And that created the observation that perhaps we ought to look at chemicals before we exposed humans to them.

And this entire area of carcinogenic testing grew. One piece was to identify chemicals, and second was a biological piece, can we do a

controlled experiment with a chemical that will let us into some of the mysteries of this very difficult process.

Q. As I understand it, you would, one, first look at the chemical itself to determine whether or not any of the components had previously been identified as a carcinogen, is that correct?

MR. KEARNEY: I object to the form of the question.

A. Well, part of the study -- type of studies were done to identify chemical carcinogens.

Q. Then you would also -- part of the process would be to use a biological system such as a mouse to test a chemical to determine whether or not it produced any type of carcinogenic result, is that correct?

A. That is correct.

Q. And it was thought this should be done before you exposed people to what might potentially be carcinogens, correct?

MR. KEARNEY: Objection to the form.

A. That has became regulatory policy.

Q. Was that not the thought behind the use

of chemical assay from chemical carcinogenesis from its inception ?

A. Yes.

Q. We take that concept back all the way to the 1920s?

A. No. In reading some of the history of that, most of the thinking about that really began to crystallize after the First World War and was really into the 1950s when people were beginning to put down on paper the idea that biological testing might be a good thing to do before putting things in the public domain.

Q. What literature are you referring to that suggested that to you?

A. There are some reports that are reports -- World Health Organization reports, reports by our own Food and Drug Administration, reports of panels of the National Academy of Sciences around that time which, if you read through them, you sort of see how the thinking evolved during that era to give support to the view that carcinogenesis bio-assays would be a useful thing to do.

Q. Getting back to the actual bio-assay itself, using the mouse to determine whether or not a

particular chemical might be carcinogenic, is there a point in the mouse's life where you use the particular chemical? And do you do it from the time it's born? Do you wait until it's three months old or a year old? I don't know how long a mouse lives.

MR. KEARNEY: Off the record.

(Discussion off the record.)

A. The protocols for the skin painting bio-assay were in our laboratory -- in most laboratories held fairly constant so you could compare results. It was generally, treatment began generally with a six-week old mouse, which is late adolescence. And we would usually run them 18 months to two years. But a two years old mouse is a very old mouse. By the time two years goes, if you start with a population of 50, you could have half of them dead just because of old age by the time of two years. So the usual was from six weeks of age to 18 months. Then you would have good survival and have a good reasonable chance of getting results.

Q. Why would they choose six weeks as the point to begin using the chemical on the particular mouse?

A. Because then the animal was sexually

mature, the hormonal status had settled down to a mature stage, and that was the length of the bio-assay.

Q. And the specific work you were doing was with respect to smoke condensate?

A. That was one of the pieces.

Q. That work was being done for whom?

A. National Cancer Institute.

Q. What, if any, results did you get with respect to the smoke condensate?

A. A whole bunch. It was a very extensive program.

Q. Let me ask you a simple question and we'll cut through a lot of the complexity of it. Did the bio-assay that you were performing with respect to the smoke condensate produce tumors?

A. Yes.

Q. And pathologically what types of tumors did you find?

A. They were both papillomas and squamous cell carcinomas.

Q. With respect to these particular bio-assays that you performed with smoke condensate, we're talking 1964?

A. Between '64 and '69 was when that main work was.

Q. Did you determine whether or not smoke condensate was a chemical carcinogen?

MR. KEARNEY: I object to the form of the question.

A. The two major findings -- I guess three major findings -- two major findings that we came up with was that in repeating what an awful lot of other people had done up to that period of time we found that if one painted a fairly high dose of a cigarette smoke condensate on the back of a mouse a couple of times a week, it acted as a weak carcinogen. You ended up with 20 percent of the animals getting tumors, a few animals with tumors and carcinomas. The other thing we found was when we took the condensate and treated it like a tumor promoter, it worked very well as a tumor promoter.

Q. Let me see if I understand. There are two aspects. One is whether or not it's an initiator of tumors, and one is as a promoter of tumors?

A. No. One was tested as a whole carcinogen. We applied it sequentially to the backs of mice for how long they lived, and counted the

tumors.

The other thing we tested was a promoter where we initiated an animal with the low dose of a carcinogen and then treated with the smoke condensate. And it turned out it did in fact give a much higher yield of tumors than when we treated the animals just with that condensate alone for a long period of time. We came to the conclusion that on the back of a mouse that tumor promotion was the dominant activity of cigarette smoke condensate.

Q. Why were these studies being performed? What was your understanding why these studies were being performed?

A. Van Duuren, who was our chief, was a chemist in the '50s, Van Duuren conducted probably the distinguished chemical work to begin to understand the chemical work of cigarette smoke condensate. The understanding was to, if we could understand the chemistry and biology of cigarette smoke condenstate, we could understand what the biological effects of this material was.

Q. If he had done the work in the 1950s, what was the necessity of continuing the work up through the '70s?

MR. KEARNEY: Object to the form.

A. It was only the chemistry that was done in the 1950s. He identified what the chemical specieation was of cigarette smoke condensate.

Q. Had there been studies in the 1950s with respect to smoke condensate in terms of bio-assays on mouse skin?

A. There were a few.

Q. Who performed those studies, to your knowledge?

A. The legendary one was the Wynder one which opened the door to mouse skin painting with cigarette smoke condensate.

Q. What other study?

A. The one performed by Arthur D. Little and published later, and the one done by Kensler.

Q. When was it done by Arthur D. Little?

A. I don't remember, I was not there at the time. But it was published in a volume which described completely the results of the studies that were done on condensate skin painting.

Q. During the period time 1964 through 1969 while you were at NYU, did you do anything else other than the bio-assay you described to us?

A. Yes.

Q. What other type of testing?

A. As I said, I was sort of the chief biologist so I was responsible for the carcinogenicity studies. There was another actively going along looking at what are called direct acting agents. And these included materials that are chemically reactive so they interact directly with biological materials, epoxides, lactones, a whole series of oxygen containing chemicals, some of which were in commercial production.

Van Duuren, being a chemist, was interested in structure relationship. So we would go through classes of chemicals only moderately different from each other and look at the carcinogenicity of those using mouse skin painting, intraperitoneal injection, and subcutaneous injection.

Q. Getting back to the findings that this smoke condensate was a weak carcinogen, you described it?

A. That's right.

Q. When you say a weak carcinogen, can you give us other types of carcinogens you would consider to be weak carcinogens?

A. Several of these alkalating agents were, some of the epoxides even at fairly high doses, higher than anyone would be exposed to it. If you had a group of 50 animals, and only 10 of them got tumors, and there were one or two tumors per animal, that would be a weak carcinogen as opposed to having all 50 animals get tumors and each animals with 10 tumors on the back.

Q. I thought you said approximately 20 percent got tumors with smoke condensate.

A. Yes.

Q. That is a weak carcinogen?

A. Yes. I think in the context we were looking at with the range of carcinogens, as I indicated, if 50 -- you have 50 animals in a group that get tumors and there are 10 tumors per animal in each of those, that would be a strong carcinogen.

Q. What is a medium or moderate carcinogen?

A. Again, it's interesting, we never, I don't think, addressed that issue. I think if something was strong we called it so. If something was on the low side, we called it weak. I don't remember we ever used that definition of a moderate carcinogen.

Q. You also determined that cigarette smoke condensate was a strong promoter?

A. That is correct. In the experiment that we did we got a tumor promotion response that was very similar to the extremely strong responses we got with the model chemical we were using as a tumor promoter at the time.

Q. Are there any products that we're aware of that you would think your average person would be aware of that are as carcinogenic as smoke condensate?

MR. KEARNEY: Objection to the form of the question. You mean that has the same degree of activity or results in the same degree of activity in the mouse skin?

MR. EDELL: You don't understand the question?

THE WITNESS: No, I don't.

Q. In terms of -- let's talk about it in terms of bio-assay studies.

MR. EDELL: Does that satisfy your objection?

MR. KEARNEY: So we all know going on, we want to make it clear everyone is in the right ballpark.

Q. With that qualification.

A. I think one has to look if -- what you are asking me is to describe potency?

Q. Potency in terms of some other carcinogens that we rightly, correctly or incorrectly, have some idea of them being carcinogenic and how carcinogenic they may be.

A. The carcinogenic literature is filled with bio-assays that have been done with extremely potent materials all they way down to extremely weak materials. When one deals with things in a single chemical, the questions one can ask are fairly straightforward. I'm not even sure that it's proper to put something like cigarette smoke condensate, which contains thousands and thousands of chemicals, which is extremely unstable, and to try to compare it to 7, 12 Dimethylbenzathracene, which for mouse skin is an extremely potent carcinogen, it's almost like apples and oranges.

Q. What I'm trying to do is to find some known carcinogenic products, if you will, that have comparable carcinogenic activity in bio-assay studies. So out of ignorance let's say: Does asbestos produce tumors in bio-assay studies?

A. Not that are relevant to what we're talking about here.

Q. So in terms of bio-assay studies, asbestos is not considered to be carcinogenic, is that correct?

A. Not for mouse skin.

Q. For another type of bio-assay study?

A. Yes, it is.

Q. Is it considered to be a strong carcinogen?

A. I'm not sure I've ever heard it described that way.

Q. Strong and weak, those were the terms that people in your profession use, as I understand it.

A. Again the asbestos issue is an extremely difficult one, because trying to determine dose and exposure for a complicated mixture is a problem in asbestos, you are into a different venue, comparing particle length, size, lung deposition.

Q. I'm talking in bio-assay studies. We are not talking about amounts or anything else. We're talking in a bio-assay study, is asbestos considered to be a strong or week carcinogen, or moderate, to use

a term that you don't use?

A. I don't think that those words are applicable out of context. You have to compare them to something.

Q. Well, what do you compare smoke condensate to in order to determine whether it is a strong or weak carcinogen?

A. Chemicals that I know give an extremely strong response at low concentrations on the back of mouse skins.

Q. All right. So there are -- what bio-assay system do you use for asbestos?

A. You use an inhalation study.

Q. We have to use something that is alive. What do we use, mice, hamsters?

A. Historically rats have been primarily used.

Q. Are rats used as a bio-assay system for inhalation studies for any other other types of carcinogens?

A. Almost universally rats are used for the source or animals for inhalation studies.

Q. Are there any known chemicals that are used in rat inhalation studies that are known to be

strong carcinogens?

A. Yes.

Q. What are they?

A. One of them is Bischloromethylether.

Q. Is there a way to shorten that? What would you refer to that in the lab?

A. It's called BCME in the trade.

Q. Let's compare asbestos to BCME. We know BCME is a strong carcinogen in the rat inhalation studies. Let's see where asbestos is compared to BCME, whether its weak or strong.

A. If one looks at the kind of exposures one might find out in the world or in the workplace, BCME is a far, far stronger carcinogen than asbestos in the bio-assay system as it's being looked at.

Q. I had a feeling that that was so. But compared to BCME. We know it's far stronger than asbestos. Let's say BCME is a strong carcinogen, is that fair?

A. That is correct.

Q. When compared to BCME would you consider asbestos to be a weak carcinogen?

A. That is very difficult. I can't equate the two. And the reason I can't is that if they were

both chemicals and I could do the measurement on what the doses were, what the exposures were, one might be able to to compare them. But you are asking to compare a fibrous material to a volatile organic material. And from a relative potency point of view it's extremely difficult to do that.

The only thing one can say is that if you look at how the exposures that one might expect in the ambient air or in the workplace, compare that, you would get far fewer tumors from those kinds of exposures from asbestos than from BCME.

Q. So you would consider to be a weak carcinogen?

A. I couldn't say that.

Q. Would you consider it a moderate or strong carcinogen?

MR. KEARNEY: Objection. I think he has given an answer.

A. I think it would be inappropriate or inaccurate for me to put that label on it given the argument I have just given you.

Q. Are there any other fibrous materials that are considered to be carcinogens other than asbestos?

A. A poster I saw Monday afternoon at a toxicology meeting -- apparently there are some new refractory fibers used in some of the new refractory materials that are being put together. There was an initial report of carcinogenicity of those materials that gave rise to lung tumors when rats were exposed.

Q. You haven't seen those studies?

A. I saw the poster of it, I saw the graphs and charts as they were display at the meeting I was at.

Q. What you are telling us is there was no way for you to tell us whether or not asbestos is a strong or weak carcinogen in bio-assay study? Just give a yes or no.

MR. KEARNEY: I object to the form of that question. I instruct you you are not limited to yes or no answers. It's my belief that you have answered that question as was put in many different forms. You can answer it again if you'd like to, but you are not limited to yes or no.

Q. You are not limited to yes or no if you cannot answer it yes or no.

MR. KEARNEY: You are not limited

to yes or no no matter what. Mr. Edell can't tell you at a deposition how to answer a question.

MR. EDELL: My acquiescing to his direction doesn't mean that I think that it's correct.

A. In order to compare the areas your probing towards. One needs to compare things that are the same. If the data on fibers are published, if we get data on fiberglass I think with that collection of data one might be able to rank those materials. But to call a material simply a weak or strong carcinogen out of context is just plain scientifically wrong.

Q. So you can only call it a weak -- let's assume that there is no other mineral other than asbestos that causes tumors, cancer in laboratory animals. When you compare that with all the other bio-assay studies where they tried to produce tumors in animals using other types of fibers, wouldn't you consider asbestos to be a strong carcinogen?

MR. SIRRIDGE: Object to the form.

A. As I said, I think the strong or weak carcinogen has to be placed in a context.

Q. Give me the context you put it in for the

purpose of discussing cigarette smoke condensate.

A. I thought I had.

Q. You told me the relationship to other chemicals that caused other cancers.

A. In that particular assay system.

Q. What I'm trying to find out in this particular assay system, in rats, have there been any other inhalation studies in rats from any other mineral other than asbestos?

A. I indicated there was ceramic fibers, I think glass wool has been looked at. But I don't know what the results of those were. And in order to make a reasonable judgment of that, I would have to see that data, study it, and make a relative judgment what the relative potencies were.

Q. If you saw the results in relation to rat inhalation studies for rats for glass wool, and ceramic fiber, and asbestos, you could tell us if asbestos in that model was a weak or strong carcinogen?

A. I could rank them.

Q. My question was whether it was a strong or weak. Not stronger or weaker.

MR. KEARNEY: Objection. Asked and

answered.

A. A strong or weak carcinogen just labeled as such out of context is of no scientific meaning.

Q. In the context of that particular bio-assay?

A. I told you I could rank them in that bio-assay and say this one gave the top response and this one gave the lower response.

Q. Isn't that what you are doing with respect to smoke condensate? You are comparing it to a chemical that gives a high response? And compared to one that gives a high response, you are saying it gives a weaker response? Is that correct?

A. That's right.

Q. Why is it that you can do it for smoke condensate but you can't do it for fibers?

A. I said if I saw the data set, I could make a judgment.

Q. The same with respect to smoke condensate. All you are giving us is a relative description relative to a chemical with a high response; cigarette smoke condensate in rat studies is considered to be weaker, correct?

A. In the context of comparing materials and

responses in the mouse bio-assay, that is cigarette smoke condensate is a weak carcinogen in comparison to other materials that give much higher responses at lower concentrations.

Q. So it's a relative term, not an absolute term?

A. That's right.

Q. So if ceramic fibers, and glass wool, and asbestos hypothetically all produced the same number of tumors in animal, rat inhalation studies, you wouldn't know whether or not all of them are strong or weak carcinogens, is that correct?

A. That's correct.

Q. Even if every one of the rats developed tumors, significant numbers of tumors, is that correct?

MR. KEARNEY: Are you assuming equivalent doses and equivalent applications?

MR. EDELL: Absolutely.

Q. Isn't that what we're talking about? Let me back up. We have rat inhalation studies. We're using ceramic fiber. We're using glass wool, and we're using asbestos. Every one of the rats develops 10 tumors, okay, everyone of them, all 50 of them.

You can't tell us whether or not ceramic fiberglass wool and asbestos are strong carcinogens in that bio-assay study?

A. It relates to the potency to the dose. You can take a very potent carcinogen and give a low dose and get very few tumors. You can raise the dose and get more tumors.

Q. How do you decide what dose to use?

A. In carcinogenicity studies, the dose is again selected so that the animals will not be negatively affected by the toxicity of the material you are applying.

Q. In other words, it won't kill them by giving it to them?

A. More than that. One of the guidelines is you can't have a reduction of more than 10 percent in the weight gain over the life of the animals.

Q. Let's assume, using the same protocol with respect to ceramic fibers, gas wool, and asbestos, you are going to give the animals a nontoxic dose. 50 rats using the same protocol developed 10 tumors all. 50 of them developed 10 tumors each. Are these considered to be strong carcinogens or not in that Bio-assay study?

A. I think all you could say is those three materials are of equivalent potency.

Q. But you couldn't say whether or not they were strong carcinogens?

A. Not out of context.

Q. What other information would you need in order to make the determination whether or not in that bio-assay study these would be considered strong carcinogens?

A. I think one would need to know the kind of relationships of exposures that one might expect out in the ambient air.

Q. But we're not talking about the ambient air, we're talking about in this particular rat inhalation study. Under those circumstances is it considered to be a strong or weak carcinogen if it produced 10 tumors in all 50 rats?

A. Out of context it's not possible. The only thing as a scientist I would be willing to say is that those three materials were of equivalent potency, and it resulted in whatever the tumor yield was in those animals.

Strong and weak, when they're used out of context like that are simply not -- scientists can't

deal with that kind of imprecision. What you are asking is to float a balloon up that has no boundaries and no precision on it, and I can't and won't do that.

Q. So, for example, in dealing with the situation of smoke condensate we're dealing with a chemical, right?

A. We're dealing with a whole bag full of chemicals.

Q. And it is only considered to be a relatively weak carcinogen because it is being compared with other chemicals that are much more carcinogenic in that particular bio-assay study?

A. That is correct.

Q. Not because it won't end up being a significant carcinogenic chemical when used by a human being?

MR. KEARNEY: I object to the form.

Q. Correct?

A. There is no way to make that extrapolation.

Q. No way to determine whether it will be a strong or weak carcinogen in human beings?

A. I'm sorry?

Q. Whether or not in a human being the smoke

condensate would result in it being a strong or a weak carcinogen in human beings?

A. I don't think there is any way to make the extrapolation in the first analysis. And in the second analysis, human beings aren't exposed to cigarette smoke condensate.

Q. When one inhales smoke -- you inhale smoke if you are smoking?

A. If one smokes; some people do.

Q. Let's assume a person is inhaling smoke. There is a deposition of various materials within the lung, is there not?

A. That's true.

Q. With respect to the materials that are in the lung, what chemicals are not found in the lung when a person smokes that are found in smoke condensate?

MR. KEARNEY: I object to the form of the question.

(Question read.)

Q. Do you understand the question?

A. Yes.

MR. KEARNEY: I didn't understand the question.

MR. SIRRIDGE: I still don't.

MR. KEARNEY: The question is incomprehensible as stated.

Q. Doctor?

A. I think the basic issue is the complexity of the material. We do not understand the complete chemistry of cigarette smoke condensate. We do know some of the chemistry of it. With respect to your question, many, if not most, of the chemicals that we know in cigarette smoke condensate are not naturally occurring material in the lung.

Q. I know they're not naturally occurring. The question is: We have smoke from a cigarette, part of it goes into the lung, part of it ends up as smoke condensate. You don't use cigarettes to get smoke condensate, is that correct?

A. I'm not quite sure what you are driving at.

Q. How do you get smoke condensate?

A. Smoke condensate is obtained in a mechanical process where you have a smoking machine. The smoke is drawn into a cold trap, and the entire mass of that smoke is condensed under very low temperature. And that is redissolved and that becomes

the material of the test on the back of a mouse.

Q. But those chemicals that end up in the smoke condensate came from the cigarettes that were being burned, is that correct?

A. That is absolutely right.

Q. It's the same smoke that one would bring into one's body if they inhaled it, isn't that correct?

A. The smoke?

Q. The smoke is the same?

A. That's right.

Q. What I'm asking you is: What chemicals are found in smoke condensate that are not found in the smoke that is brought into the lungs of smokers?

A. I don't know the answer to that directly. What we do know is that cigarette smoke condensate is a chemically very unstable material, so that generically I would say that there would probably be a lot of chemicals in cigarette smoke condensate that in fact might not be in fresh smoke in the lungs.

Q. Do you know whether or not, getting back to the question, there are any chemicals that one does not bring into one's lungs when one smokes a cigarette that one would get in the mechanical process and

distillation process of smoke condensation?

A. I don't know the answer for that for sure.

Q. Is there any literature on that?

A. It would be almost impossible to determine that. You would have to do the chemistry in situ on the smoke. And once you do that it's not smoke anymore, I'm not sure that you could really compare that.

Q. Am I correct, sir, once the smoke enters a smoker's lungs that at some point in time it no longer remains smoke, or a portion of it no longer remains as smoke; isn't that correct?

A. Smoke is a suspension of particles.

Q. The particles are actually deposited on the lungs or a fraction of them?

A. That is correct.

Q. And if one were to examine the particles, one would find certain chemicals in those particles, would they not?

A. Yes.

Q. Do you know whether or not with respect to those particular particles that remain in that smoker's lungs, whether any of the chemicals -- any of

the chemicals found in smoke condensate are found in those particles?

A. I don't know that.

Q. Does anyone know?

A. I don't know.

Q. They don't know whether they are and they don't know whether they are not; is that correct?

A. As I indicated earlier, because of the enormous instability of cigarette smoke condensate, the expectation would be that the chemistry of particles that would ultimately lodge in the lung and the chemistry of cigarette smoke condensation that is used to paint the back of the mice might be substantially different.

Q. Would it be less or more carcinogenic?

A. I would have no way to make that judgement.

Q. Does anyone know?

A. I don't know that anyone knows.

Q. 1969 we leave NYU?

A. No, I stayed at NYU, 1969. Cigarette smoke condensate became less important.

Q. What did you start doing after that?

A. During the time I was at NYU, I was

brought in to look at developing some new kind of methodology to study tumor promoters. The study of tumor promotion was a primary interest in our laboratory, again because Van Duuren was a chemist who was interested in isolating the chemistry of a potent material that was used as a test substance. And I was a cell biologist looking at how to apply cellular systems to see how tumor promoters act. And that carried during the 10 years I was at NYU. And looking for assays of tumor promotion and the mechanism of how tumor promoters act biologically.

Q. Tumor promotion, are we talking about the promotion of tumors or development of tumors?

A. What we're talking about is what the biology is of these late phase events of which is tumor promotion. That was the process by which these events happen that ultimately lead to tumors.

Q. You say late stage events. That suggests there is an earlier stage event. Is there?

A. In the classical mouse skin study, initiation is an early stage event and promotion is a second stage event.

Q. This gets back to one of my earlier questions, whether or not smoke condensate is, in the

context of a carcinogen, is it a weak initiator but a strong promoter?

A. I'm not aware that there is any evidence at all demonstrating that cigarette smoke condensate is an initiator.

Q. Are there any chemicals that are considered to be initiators?

A. Yes.

Q. What are they?

A. There are a class of aromatic hydrocarbons, Benzoate pyrene.

Q. Is that found in cigarette smoke?

A. Yes. And again sample chemicals. This 7,12 Dimethylbenzathracene, it's a laboratory organic hydrocarbon, but we use it because it's potent. There are other materials like urethane, which is not in cigarette smoke condensate, other materials like nitrosamines, all of which can be initiators for mouse skins.

Q. Are there nitrosamines in tobacco smoke ?

A. Not that I know of.

Q. How do we determine whether the aromatic hydrocarbons found are initiators or not?

A. A lot of them have been tested in this

set initiation sequence. And then we use a phorbal ester and it's a sample tool to look at aromatic hydrocarbons. And much of what we did with Van Duuren was look at the chemistry of a wide variety of aromatic hydrocarbons to see if they were initiators or not.

Q. All of the aromatic hydrocarbons found in cigarette smoke were found not to be initiators?

A. No.

Q. Are there aromatic hydrocarbons found in cigarette smoke found to be initiators?

A. Yes.

Q. What are they?

A. Benzoate pyrene is, Dibenz AH anthrazene. I don't remember all of them. But there are a number of aromatic hydrocarbons which have been detected in cigarette smoke condensate. If one does a mouse skin painting, one sees they're in fact initiators. There are a large variety of them that are inactive. And then there are some aromatic hydrocarbons that in fact block the effect of other aromatic hydrocarbons. So you have those that are initiators, a lot that have no biological activity, and a number of them that are anti-initiators.

Q. Getting back to the initial question. You said smoke condensate that contains these aromatic hydrocarbons does not have any type of initiating effect.

A. My understanding, the few things I've seen were tested. If you do an initiation promotion experiment, treat an animal with cigarette smoke condensate, and promote, cigarette smoke condensate has never been found to be an initiator as a material, cigarette smoke condensate. Part of the reason may be that the balance between the pluses and the minuses, the things that depress it may be strong. You have to say that it doesn't display any tumor initiating activity.

Q. Would that suggest that the smoke inhaled by a smoker would not be considered to be an initiator?

A. I don't think there is any way to compare, that it would be compared.

Q. Why is it that you do the bio-assay study? What is the purpose if you can't extrapolate from it in some way or form to human beings?

A. The understanding was to try to understand better the chemistry and biology of what

happens. In the best of all worlds, if you could find a few materials that were highly potent and you could remove them, that might have some positive effect. There was no guaranteeing it would, but at least it is a way to start.

Q. Why would you even think that it might have a positive effect if you could remove those, if you cannot extrapolate at all from animal studies to human beings?

A. I think what happens is one takes the best system one has knowledge of. And if, in fact, you can find cigarette smoke condensate that is not as potent, I think it's a reasonable assumption to say "Let's try it over here." Its very difficulty to extrapolate. It's a long way between cup and lip. But in the absence of any other information, it's a reasonable thing to try.

Q. Why?

A. I think the whole -- the National Cancer Institute ran a program for many years on trying to develop a less hazardous cigarette.

Q. There are people who believe that animal studies, be they smoke condensate studies on mouse skin or otherwise, have significant implication for

what may happen with the same substance in human beings, is that correct?

MR. KEARNEY: I object to the form of the question.

Can I have it read back.

(Question read.)

A. I suspect there are people who have that view.

MR. KEARNEY: Do you have anyone in mind?

Q. Like the National Cancer Institute, do you think that is part of the reason they were doing some of these bio-assay studies?

A. I don't know who you are talking about. The National Cancer Institute is 25,000 people in Washington.

Q. So you had no understanding when they were paying for all these studies to be done, it might not have any application to human beings. It was going to be only pertinent to the poor little mice that were being exposed?

A. No.

Q. What was your understanding?

A. The basic issue was to try to understand

as much as we could again about the chemistry and biology of the cancer process. So if there were ways to intervene one might be able to do that. That within the context of understanding the enormous difficulty of trying to extrapolate from cigarette smoke condensate to mice backs and from the mice backs to human beings. So the purposes of this is so you could possibly reduce the carcinogenicity of smoke condensate or produce a cigarette that would produce less toxic or less carcinogenic smoke condensate, so you could develop what might be a safer cigarette for use by human beings. That was the prescribed intention of the Cancer Institute for many years.

Q. And if the bio-assay had no application to human beings, why would you use animal bio-assay?

A. The animal bio-assay would give us a set of information that we could make some application to humans. And I think the difficulty in dealing with that is understanding just how close or how far that relationship is away. It clearly does not have zero relevance. I think the question is, however, are you willing to say that it's completely relevant. My feeling is from a biological point of view and chemical point of view, the relevance is very

difficult to establish. But since there is nothing in between, we take the best tools we can get, the best information we can, and we try to then apply it, even understanding that we're leaping across a great big gulf of lack of understanding.

Q. Is it fair to say the best guess we can make with respect to carcinogenicity in human beings in terms of biological studies is to use animal studies, is that correct?

A. I think we have come a along way since the '60s when we were designing these. I think our understanding of how we deal with chemical exposures in the environment and what kind of risks those may pose to humans, our technology has became a lot better. And I think that in order to make those kinds of judgments, one would need -- in addition to the animal bio-assay studies, one would like to have metabolism and disposition studies. One would certainly like to know what the real exposures are to people. And I think when one has a full body of those kinds of data, one can come a little bit closer about making judgments about what the impact on humans might be.

Q. With respect to this metabolism study,

when did that become available?

A. Oh, people have been looking at metabolism for 25 years.

Q. When you are talking about real exposure, how do you determine real exposure?

A. There are a number of ways to monitor it. You do sputum assays, measure the cells that occur in the sputum to see what the chemical concentrations are in the sample.

Q. That is after the human being is exposed to the chemical?

A. That's right.

Q. Let's assume we have a chemical that is a weak carcinogen in the mouse bio-assay but is a strong promoter. The product is not on the market so we don't have people who are exposed to it, yet we can't do that sort of study to see what their exposure is, right?

A. That is true.

Q. How do we decide whether or not the animal bio-assay has some significance with respect to the people who might in the future be exposed to that particular chemical?

A. I think one of the important things would

be to compare the metabolic profile in animals and in humans. And now there are tissue banks of liver cells and operating room and autopsy tissues that are available.

Q. Without that, let's assume that you don't have that because we didn't have that 25 years ago, right?

A. That's right.

Q. Without having the availability of the metabolism studies, what else can you do to see whether or not the animal study has some significance for exposing human beings to the same chemical?

A. When you are looking at that vintage of time, not an awful lot other than the bio-assay.

Q. Not an awful lot other than -- is there anything?

A. Other biological activities of that material in enzyme systems, in other biochemical systems where you might be able to detect whether that chemical caused a specific change in some event.

Q. Give us an example of the type of enzyme study that was being performed 25 years ago that might reflect whether or not a product might be carcinogenic in human beings?

MR. KEARNEY: Are you making this witness a state-of-the art witness?

MR. EDELL: I'm going through background, what you knew.

MR. KEARNEY: As far as I'm concerned whatever you touch on at the deposition is fair game at trial.

MR. EDELL: You do whatever you want to do. I'm going through his background.

MR. KEARNEY: Go ahead.

A. What the enzyme studies would tell you relate to the toxicity of the material.

Q. I'm talking about carcinogenicity of material. How might it help you determine whether the product would be carcinogenic in human beings?

A. At that vintage of time this was probably nothing else other than the bio-assay.

Q. And 25 years ago and before, was the bio-assay an accepted standard by which to evaluate whether a chemical might be hazardous to a human being in terms of its carcinogenicity?

MR. KEARNEY: Accepted by whom?

MR. EDELL: The general scientific community.

A. 25 years ago the bio-assay was really immature. It was in fact demanded at the time by the Food and Drug Administration.

Q. For what purpose?

A. For testing food additives and drugs.

Q. With respect to carcinogenicity?

A. And toxicity, the bio-assays were done to determine all the biological effects a material could have whether or not.

Q. And it was used as a screening process before a product could be sold?

A. That is correct.

Q. And if a product were found to be a weak carcinogen and strong tumor promoter, it wouldn't get a clearance to be sold?

A. If it were a food additives or drug, it probably would not.

Q. Anything that would be consumed by a human being at that time?

MR. KEARNEY: At any dosage?

A. Anything under regulatory cognizance would not be.

Q. Anything the government had control over?

A. Anything that you needed to have a

government license or some sort of government approval to sell. And at that time it was pesticides, drugs, and food additives.

Q. Did you have an opinion at that time as to whether or not that was a reasonable standard?

A. Yes.

Q. Was it a reasonable standard?

A. I had an attitude. And I think that is a reasonable way to go about a testing protocol to get information relating to the safety of materials.

Q. And to determine whether or not people should be exposed to it?

A. To give the regulator a body of information that will allow them to make that decision.

Q. As to whether people should be exposed to it, correct?

A. As to whether it should be allowed into the marketplace.

MR. EDELL: Why don't we break for lunch. It's 10 after 1:00.

MR. KEARNEY: Fine. We will get back at 2:00 o'clock.

MR. EDELL: 2:00 o'clock.

(Whereupon, at 1:10 p.m., a luncheon recess was taken.)

oOo

AFTERNOON SESSION

2:15 p.m.

A N D R E W S I V A K, resumed the stand and testified further as follows:

MR. EDELL: Doctor, we're back again, the same admonition I gave you this morning for the duration of this deposition today and if we end up going tomorrow. You understand you are still under other.

THE WITNESS: I understand.

EXAMINATION (cont'd) BY MR. EDELL:

Q. Getting back to the chronology of your work as set forth in your CV which we have marked as P-1. I believe we were up to 1974, correct?

A. Right.

Q. Up to 1974 did you do any work other than Biochemical work and bio-assay work?

MR. KEARNEY: Object to the form of the question.

A. Well, the work covered a whole range of things, from bio-assay, cell biology, animal

pathology. The latter part of that time was mostly a mixture of biochemistry and the study of tumor cell promotion.

Q. Did any of your study deal with carcinogenisis in human beings?

A. No.

Q. So you've had no experience with respect to carcinogens in human beings, at least up to '74?

A. You have to define that.

Q. Cancer in human beings.

Did you have any experience with respect to cancer in human beings, be it in the form of how to treat it, how to identify it, what would be the cause of it, any of those?

A. Yes.

Q. Any of the work other than the work that you did at Arthur D. Little with respect to the anticancer drugs?

A. Some of the work at NYU.

Q. What work at NYU related to cancer in human beings?

A. The BCME work in particular was related to observations that showed worksite observations that showed a higher incidence of cancer in men in places

that used that chemical than in places that they didn't. And that was the impetus for looking at that whole class of chemicals.

Q. Had there been a study of workers exposed to BCME, an epidemiological study?

A. The epidemiological study came later. The reason we got interested in it was that there was anecdotal information coming out from this set of factories. It was sort of preepidemiology, but it was human information.

Q. In other words, there appeared more lung cancers?

A. In the workers with this particular chemical than, say, a cohort of workers who were not exposed.

Q. I understand the chronology. First, there are the observations by the doctor, the factory doctor or otherwise, who identifies what they perceive to be a significant number of lung cancers in the workers exposed to the BCME?

A. Right.

Q. Then two things happen. An epidemiological study begins as well as your work at NYU, correct?

A. Yes, our group began working.

Q. Specifically what did you do to identify whether or not BCME was a cause of the cancer, the lung cancer identified in these BCME workers?

A. Our role was looking at BCME and a class of related chemicals to determine what the carcinogenic response was in the various animal systems we looked at.

Q. My question related -- my original question related to what work did you do to determine whether any particular substances caused cancer in human beings?

A. That was not related to that. It was after the fact that the observation was made that there might be a relationship between exposure and human cancer.

Q. And what, if anything, in the work that you performed related to confirming the fact that these people were developing lung cancers as a result of their exposure to BCME?

A. All our findings were that on a molecular and concentration basis that BCME was an extremely potent carcinogen.

Q. What relationship did that have to the

workers?

A. What it was was that this was a material that was extremely reactive from a point of view. So it didn't relate at all to understanding what the cause of the tumor was. What it gave us was some understanding as to how the tumor occurred because of the extreme reactivity of this material.

Q. In what way could it tell you how the tumor occurred in human beings?

A. What it told us was that this was an extremely reactive chemical that was very potent, not not only in systems that we did, but in others of our collaborators at the laboratory. And it was highly likely that because of the extreme reactivity of this material in a biological system, we looked that it could be implicated as the causal material in the human situation.

Q. So if there is a strong reactivity in bio-assay studies then we can then take it and say it has some significance to human beings. Is that what you are telling us?

A. If you have an appropriate cluster of information, the most significant piece --

Q. What is the cluster of information?

A. We had bio-assays on. And I didn't do them all, it was part of a team effort. Whichever organ system we used to test skin painting, subcutaneous injection, or, most importantly, because the route of inhalation was the one that humans used, the tumors could be produced -- tumors could be produced quickly and with high yield.

And the fact that we had that set of information, the fact that we had the set of information that said if you dose an animal at the same route, inhalation, that the humans were exposed to and you got the same kind of tumors in those animals, that that made a box of information that supported the contention of how this chemical gave rise to tumors in human beings.

Q. Is it rather the strength of the evidence as opposed to simply the fact that you are using bio-assay?

A. Oh, yes.

MR. KEARNEY: Object to the form of the question.

A. Yes. I think that just to take a bio-assay, and because you get a positive and you run off and make a decision is not valid. I think one has

to take the whole cluster of information. And dose route is a very important part of this. What one would like ideally to have is the route of administration in the experimental animal be the same as in human, and in fact that the tumor type in the animal be the same as it is in human. We had that with this Bischloro/methylether.

Q. So unless you have it in terms of the same route of exposure, then you cannot extrapolate from animal studies to human beings, is that what you are telling us?

MR. KEARNEY: Object to the form of the question.

A. What I'm saying is that you are dealing with different amounts and quality of information.

Q. Right.

A. Your most ideal would be to have this whole cluster of information all together. The ease and the certainty that I, or I suspect, a lot of my colleagues would have in making jumps from animal data to human situations is going to diminish as one moves further away from route and type of tumor, appropriate dosages. As you lose those variables, then the degree of certainty that I would have, at least in making the

jump from an animal experiment to a human, is going to be less and less.

Q. Regardless of what other additional information you might have in terms of epidemiology or clinical observations?

A. That is part of it, that is part of the cluster of information.

Q. So if you have strong epidemiological information and you have animal skin painting studies that produce positive results, but you don't have maybe inhalation studies, that might be enough.

MR. KEARNEY: Object to the form of the question.

MR. SIRRIDGE: Object to the form of the question.

A. For each situation one needs to lay out what the material is, what the set of data are. I don't think there is a generic answer like a chinese menu. I need one of these and one of these to make a judgment. That's been the way the entire regulatory apparatus of the country is put together, judgment based on a chemical-by-chemical basis.

Q. What chemicals cause cancer in human beings?

A. My recollection is that the last list that was published by the National Institute of Environmental Health Sciences listed 13 or 14 known human chemical carcinogens. I don't think I can list them all off the top of my head.

Q. In your opinion, can you name any chemicals that, in your opinion, cause cancer in human beings?

A. Benzene is on that list, arsenic is on that list, Bischloromethylether is on that list, vinyl chloride is on that list.

Q. Is it fair to say if a substance is on that list, then you consider it to be a cancer-causing substance in human beings?

A. I agree with the decision that was made by the National Institute of Environmental Health Sciences in listing those chemicals.

Q. So your answer is yes?

A. Yes.

MR. KEARNEY: Object to the form of the question.

Q. Does asbestos cause cancer in human beings?

A. Yes.

Q. How do we know that?

A. That's one of those situations where one has cancer produced in animals using the route of inhalation and the kind of tumors one gets in humans as one gets from comparing the epidemiology data.

Q. Does cigarette smoking cause cancer in human beings?

A. Frame that, in what terms?

Q. In terms of people who smoke.

A. The Surgeon General's Report for 20, almost 30 years have shown that there is an increased risk of dying from lung cancer that is strongly associated with smoking.

Q. I know that. They also say that cigarette smoking is the most preventable cause of lung cancer in the United States today. Is that correct?

A. That is correct.

Q. So they also say that not only is it a significant risk factor, that in fact according to the opinion of the Surgeon General, cigarette smoking is a cause of lung cancer in smokers. Is that correct?

A. That is a statement made by the chief public health officer of the country.

Q. And that is what has appeared over the last 20 years in the various publications by the Surgeon General's office on cigarette smoking and health, is that not correct?

A. That's correct.

Q. Do you agree with the statement that cigarette smoking is a cause of cancer in human beings?

A. Taking that statement as a public health statement related to the association of death from lung cancer, that is an appropriate statement.

Q. No. Looking at the whole cluster, as you described it, as evidence, is it your opinion that cigarette smoking is or is not a cause of lung cancer in human beings, yes or no?

MR. KEARNEY: Object to the form of the question.

MR. EDELL: If you can't answer that question yes or no, then we will get the right Honorable Judge Hedges on the line, as you described it before.

MR. KEARNEY: You can answer that question any way you would like to answer that question until a judge tells you otherwise.

A. I have indicated to you that the statement that the Surgeon General makes with respect to the public health judgment based on the association is a correct one, cause in science has a much narrower definition than a public health definition. And you are asking me sort of without definition as to where I put that cigarette smoking causes cancer just to make it a general overall statement.

Q. Is it scientifically probable that cigarette smoking is a cause of lung cancer in human beings?

A. Are you asking me as a scientist with respect to a cause and effect relationship in the strict etiological sense or as a public health determination?

Q. Dr. Sivak, in your opinion, is it more probable than not that cigarette smoking is a cause of lung cancer?

A. And I've indicated to you there are two frames to put that in. One is the scientific frame of causality which scientists understand as the need to set causality, or a public health statement. The surgeon General says that based on this information, this is the public statement I'm going to make.

Q. Is it your testimony that the Surgeon General has not reached the conclusion based upon scientific causality that cigarette smoking is a cause of lung cancer in human beings?

A. I think that is true. I think he's based his association, as I would as a public health officer if I saw a relative risk ratio of 15 to 1 whether I understood whether it was truly the etiological cause of it, I think as a responsible public health officer, I would say as a 15-to-1 risk ratio it suggests an argument for not to smoke.

Q. According to the chemical studies and animal studies does that increase the likelihood that cigarette smoking is the cause of lung cancer?

A. If one looks at basic animal study, the basic evidence for cigarette smoke is lagging.

Q. When you look at the chemical studies and bio-assay in conjunction with the epidemiology, does that strengthen the position that cigarette smoking is a cause of lung cancer in human beings?

A. I think that the amount of added confidence that it gives to a public health officer to make a judgment is relatively small given the strength of the epidemiology data.

Q. To you as a scientist does that increase the likelihood that cigarette smoking is a cause of lung cancer in human beings?

A. We're mixing apples and oranges.

Q. Let me see if I can make it simple. Based upon the chemical studies of smoke, we know that there are known carcinogens in tobacco smoke. Is that correct?

A. Correct.

MR. KEARNEY: Based on what?

MR. EDELL: Upon the chemical studies.

MR. KEARNEY: Only on chemical studies?

MR. EDELL: You don't understand the question?

MR. KEARNEY: Everything is happening so fast I didn't understand the question.

Q. Did you understand the question, sir?

A. We'd better go back over it.

MR. EDELL: Would you read that back.

(Question read.)

Q. How many carcinogens based upon the chemical studies of tobacco smoke do we know cause cancer in human beings?

MR. SIRRIDGE: I'm sorry, could you repeat that question.

MR. EDELL: If Mr. Sirridge wants it repeated, it means it really didn't make any sense.

THE WITNESS: He's right.

Q. How many of the chemicals in cigarette smoke cause cancer in human beings?

A. I don't recall that any of the chemicals that I know that are in cigarette smoke are on the National Institute of Health list of documented human carcinogens, as a matter of fact.

Q. So to the best of your knowledge, there are no known chemicals in cigarette smoke that cause cancer in human beings?

MR. SIRRIDGE: I'm going to object to the form of that, misstating the testimony.

A. What I am saying is I am taking as the list of known human carcinogens those 12, 13, whatever. And the National Institute of Health Sciences publishes in their annual list of carcinogens

that these 13 are known human carcinogens. My recollection, and it's only a recollection, is that none of the chemicals that I am aware of that are in cigarette smoke condensate are on that list.

Q. Are there any chemicals that are identified in cigarette smoke that are promoters of cancer in human beings?

A. We don't know that promotion -- well, let me step back.

Q. If you can't answer that, tell us you can't answer.

A. The question assumes some things that are not true or that may not be true. You are saying are there human tumor promoters in cigarette smoke condensate? We are not sure that there is something like promotion in humans, number one. Number two, promotion is not a mechanism, promotion is a method of treatment. Your question implied a mechanism.

Q. What is a co-carcinogen?

A. A co-carcinogen is a material that when applied with a carcinogen at the same time increases the yield of tumors beyond the carcinogen alone.

Q. Is it fair to assume there is no known co-carcinogen in tobacco smoke that causes or

contributes to the number of cancers that might be found in human beings?

A. We don't know enough about the mechanism to understand whether that in fact operates in humans.

Q. Basically what you are telling us is that the chemical studies with respect to smoke condensate are negative with respect to cigarette smoke and cancers, is that correct?

MR. SIRRIDGE: I object to the form of the question.

A. What I have said is of the chemistry we know about cigarette smoke condensate, my recollection is that there are no known human carcinogens as identified by the Federal Government in that list of chemicals that is in cigarette smoke.

Q. I'm not relegating you to that little list, I'm asking whether or not in your opinion there are any chemicals identified in cigarette smoke that are known carcinogens in human beings?

A. And I refer back to that NIEHS list, which I agree with, that none of the chemicals that I'm aware of are on that list.

Q. Forget about the list, Doctor.

A. But that is what I'm taking as my known

human carcinogen benchmark.

Q. So according to you there are no other chemicals other than those that are contained on that list?

A. That are recognized known human carcinogens.

Q. That are, in your opinion, cancer-causing chemicals in human beings? Forget about recognition, forget about the government. We're talking about Dr. Sivak.

A. Dr. Sivak takes as his opinion the National Institute of Environmental Health Sciences.

Q. You rely upon the National Institute of Health in that regard?

A. It's reciprocal. They partially depend on my opinion in coming to those decisions.

Q. Let me make sure I understand, because sometimes lawyers get a little bit suspect about responses when they shouldn't be.

But let me make sure that my suspicions are not warranted. Are there any substances other than those that are contained on this list that you refer us to that in your opinion are a cause of lung cancer -- or a cause of lung cancer or any other type

of cancer in human beings?

MR. KEARNEY: Object to the form of the question.

A. I don't know of any.

Q. Where in the statements in any of the Surgeon General's reports that you read does the Surgeon General differentiate between causality from a scientific perspective and causality from a public health perspective?

A. It's my view that the Surgeon General speaks as the chief public health officer of this country.

Q. I understand that.

A. And that his statements with respect to causality in this regard are in fact public health statements.

Q. And if in fact the Surgeon General -- Surgeon General's position on cigarette smoking and health was based upon scientific opinion as opposed to public health opinion, would you be surprised?

A. I don't understand.

Q. Well, you seem to suggest that there is a different test for causality when you are looking in terms of public health and you are looking in terms of

science, right?

A. That's right.

Q. And what I am telling you is I didn't see in any of the Surgeon General's reports any qualification of the Surgeon General's opinion that it was not based upon scientific causality as opposed to public health causality. Did you see any such statement?

MR. KEARNEY: Object to the form of the question. If you understand what he's saying, you can answer.

A. I guess in reading the Surgeon General's reports, and I don't know them chapter and verse and I have not read every page of every one of them. But those places where I read it, and the issue of causality comes in, it seems to me that the Surgeon General is speaking about the public health kind of causality as opposed to the scientific causality where the lineage of direct proof of a scientific proposal is supported directly by the data.

Q. Is it your testimony that from a scientific perspective causality has not been established with respect to cigarette smoking and lung cancer in human beings?

A. I think there are some gaps in information.

Q. Can you answer the question?

A. Will you repeat it, please.

(Question read.)

A. In a classical scientific perspective of the assemblage of information for absolute cause and effect, I don't think it has been.

Q. What is lacking?

A. One of the primary things is the animal experimentation. We don't have an animal model, and it's been tried and tried. We have yet to produce a bronchogenic carcinoma in the lung of an animal that has been exposed to enormous amounts of cigarette smoke for a lifetime.

Q. Anything else missing?

A. I think the other is an uncertainty that prevents one from putting together that kind of ironclad causality agreement.

Q. What you are telling us is it hasn't been proven 100 percent that cigarette smoking causes lung cancer in human beings, is that correct?

A. It hasn't been proven with respect to a scientific cause and effect lineage of proof.

Q. That there is still some gaps?

A. Yes.

Q. But from a scientific perspective, wouldn't you agree that more probably than not cigarette smoking is a cause of lung cancer in human beings, not absolute certainty but more probably than not?

MR. KEARNEY: What do you mean, "more probably than not"?

Q. More likely that cigarette smoking is a cause of lung cancer in human beings.

A. I think that if one assembles the weight of evidence from all that we know about situation, that a likely conclusion could be that cigarette smoking can cause cancer in human beings.

Q. Is it your opinion, sir, that more likely than not cigarette smoking is the cause of lung cancer in human beings?

MR. KEARNEY: He already answered that question.

MR. EDELL: Are you directing him not to answer the question?

MR. KEARNEY: Is that question different from the question beforehand?

MR. EDELL: Yes, it is.

MR. KEARNEY: How is it different?

MR. EDELL: Do you want to direct him, you do it.

MR. KEARNEY: I'll let him answer the question.

(Question read.)

A. As I indicated before from a public health standpoint.

Q. From your perspective as a scientist, okay, we understand that, so my question is clear. That's what I'm asking you. Is it your opinion that more probably than not cigarette smoking is or is not a cause of lung cancer in human beings?

MR. KEARNEY: I object to the question. I direct the witness not to answer.

MR. EDELL: Let's get the magistrate. You don't need explanations. Do you have his number?

MR. KEARNEY: Are you going to let him answer that question? You interrupted him in the middle of an answer.

MR. EDELL: If you want to get it out on the record and then we'll get the

question answered. Answer the question any way you like. But what I'm looking for is not some public health standard. I'm looking from your standard as a scientist.

Q. Is it your opinion more probably than not that cigarette smoking is or is not the cause of lung cancer in human beings?

MR. KEARNEY: I think this is argumentative, and I think it is totally improper for you to instruct this witness on how to answer a question. He can answer the question any way he likes. If you don't like it, tough. If that doesn't satisfy you, you can go to the magistrate right now. Because my position before that magistrate is you cannot tell a witness how he can answer a question. He can answer the question anyway he likes.

MR. EDELL: Will you read the question.

(Question read.)

MR. EDELL: I'm going to withdraw that question, the last question. I'll rephrase it. But it is not your prerogative to interrupt.

Q. Based upon your opinion as a scientist, are you of the opinion that cigarette smoking is more probably than not the cause of lung cancer in human beings?

A. Yes.

Q. As a scientist, Dr. Sivak, is it your opinion that more probably than not that cigarette smoking is a cause of lung cancer in human beings?

A. Yes.

Q. Dr. Sivak, as a scientist, is it your opinion that more likely than not cigarette smoking is a cause of lung cancer in human beings?

A. Yes.

Q. 1974 you left NYU?

A. That is correct.

Q. Where did you go?

A. Back to Arthur D. Little.

Q. Doing what?

A. Initially went back to start a group of investigators to take some of the technology that I had developed at NYU, bring it to Arthur D. Little to see whether or not we could set up a group that might make it a profitable piece of the Life Sciences Group, arthur D. Little, and that is the use of cell culture

systems to identify carcinogenetic toxins and promoters.

Q. What, if any, relationship did the use of cell culture systems have to lung cancer or other cancers in human beings?

A. The basic purpose of this was to use a system that you could do in a month, two, that would cost a few thousand dollars only, to identify potential new chemicals in the environment that might be hazardous.

Q. What was the purpose of doing that?

A. We were under contract to the National Cancer Institute who was interested in developing a hot battery of tests to try to replace or at least supplement the bio-assay which was going at a million dollars a pop so that if you could get information that at least could raise some flags from a public health point of view for $3,000. From a public health point of view it's better than spending a million dollars for the same answer.

Q. Did you agree with that position?

A. Yes.

Q. Why?

A. Well, I had some confidence in the

systems that I had developed that they in fact were measuring processes that at least had a biological relationship to what we understood to be cancer occurrence in animals and possibly in humans. And that it was a very useful early step to do when making judgments about new chemicals.

Q. What type of chemicals did you test with these cell cultures?

A. Our first set we looked at, I guess it was a dozen or 15 known animal carcinogens. And the purpose -- and noncarcinogens relative pairs. And this was to validate the system to make sure if in fact we tested it in a cell culture system, at least if we compared it to an animal system, that the correlation was pretty good.

Q. Did you use a smoke condensate in any way in these cell culture systems?

A. We look at only discrete identifiable chemicals.

Q. Not substances like the total substance of smoke condensate?

A. We didn't look at complex mixtures.

Q. But did you look at any chemicals that were contained in smoke condensate?

A. Yes.

Q. What chemicals?

A. Specifically Benzoate pyrene.

Q. Did the testing for the culture system confirm that Benzoate pyrene was a potential cause of cancer?

MR. KEARNEY: Object to the form of the question. What it showed is that Benzoate pyrene caused positive reaction in the assay system.

Q. And the purpose of the assay is a warning that a chemical might be a carcinogen in human beings?

A. The purpose was to provide, yes, an early warning so that additional animal studies and other questions could be raised with respect to making decisions about the chemical. Although Benzoate pyrene, as I said, was used as a test substance to validate the system since we knew it was an animal carcinogen.

Q. It's been known to be an animal carcinogen for how many years now?

A. That chemical? 55 years.

Q. For what period of time have we known that Benzoate pyrene has been in smoke condensate?

A. I guess 35 maybe.

Q. I assume you did develop an acceptable cell culture system, is that correct?

A. That is correct.

Q. What else did you do from 1974 to 1989 at Arthur D. Little?

A. After a couple of years I was made the manager of the Life Sciences section at Arthur D. Little and had management and technical responsibility for all the Life Sciences work done from the section.

Q. What year was that again?

A. Pardon?

Q. What year was that?

A. '75 or '6, I think. And after that time until 1987, I was the manager of the group.

Q. What did that mean in terms of your day-to-day responsibility.

A. I had to, one, I kept on my consulting work. I kept on for a good while as the manager of the cell culture program until I brought along a young cell biologist to whom I ultimately turned it over. I had other consulting jobs I was doing. And then from the management side I was responsible for the financial management of the section, that is to make

sure we made money and to look over the scientific quality of our reports to make sure what we sent out to the outside world was of high quality and the best that we could do.

Q. Did you become aware of the work that the Life Sciences division of Arthur D. Little was doing for Ligget & Meyers?

A. Yes.

Q. What work were you aware of that they were doing when you came back in 1974, '75?

A. There were the skin painting studies. There was a very large study that was done that was a two years old inhalation exposure study in rats. There were a variety of small tasks that we did doing toxicological evaluations of materials that were contemplated as additives.

And then I was responsible for a small mutagenicity study where we were comparing cigarette smoke condensates from different cigarettes.

Q. What was the purpose of the toxicologic evaluation and the mutagenicity study?

A. The toxicological evaluations were to provide information to Ligget & Meyers with respect to what was known about materials that they wanted to use

as humectin flavoring ingredients. We would prepare all that was known about the effects in biological systems of these materials and then provide that to them so they could use that in making their decision whether they wanted to put that in the tobacco product.

Q. What about the mutagenicity studies?

A. The mutagenicity studies were done to make a comparison from a cigarette with palladium nitride, and the same cigarette without palladium nitride. Ligget made the concentrates and sent them up to us, and we did the bio-assay on the two condensates.

Q. What, if anything, did you find?

A. We found that with the palladium condensate that the mutagenic capability on the strain of organisms that we were using that measure the kind of mutagenicity one might get from Benzoate nitrate was reduced by the palladium nitrides. We found that another class of mutants, direct acting mutants, they increased with the palladium condensate. So we had one kind of mutation that went down and another class of mutations that went up.

Q. Of what significance is that?

A. Well, it was interesting because based on the animal experimentation where there was the reduction in tumor yield, I guess the speculation was that all mutation parameters would have gone. But the fact that one went up raised some concern about what was the chemistry behind that, what was causing that unexpected upward push in a response that really had not been expected.

Q. Of what significance was it with respect to advising Ligget & Meyers on the issue of marketing or not marketing a cigarette that contains a palladium additive?

MR. KEARNEY: I object to the form of the question. I haven't a clue what that means.

A. I had never had in my whole time there ever a role or was posed any questions with respect to the marketability if the cigarette. Our role was to provide them with the technical and scientific information.

Q. Did the result of mutagenicity studies in any way suggest to you that on balance the palladium additive cigarette should not have been marketed?

A. We couldn't get further enough along to

really understand that. We did a couple of sets of experiments, and I guess that was at the unfortunate time when a lot of financial and other kind of pressures came on Ligget, and the Ligget program disappeared from ADL.

Q. What other kind of pressures were you referring to?

A. Well, they were subject to takeovers. There were all sorts of economic and corporate things going on that Ligget was in the middle of. But that early to mid-'80s, essentially the entire Ligget research program had disappeared.

Q. What contact, if any, did you have with Dr. James Mold?

A. I knew Dr. Mold from the time I came back to ADL in '74 until he retired in early to mid-'80 some time. Dr. Mold was the main scientific conduit between ADL and Ligget. His counterpart was Charles Kensler. Charlie and he were the two interfaces that made the decision what to do and collectively did things. I know Mold was the chemist. In my dealings with him he seemed always to be enthusiastic of the program, was supportive of the things that we were doing and I was doing. I felt like he seemed to be a

good husbander of the Ligget research program.

Q. Did you ever formulate an opinion as to his competency?

A. As a chemist I thought he was first class, and as a manager of the research, I thought he was very good at that too. He was not a biologist.

Q. Did you take the fact that he was not a biologist to in any way adversely affect any decision-making process that he made or participated in?

MR. KEARNEY: I object to the form of the question. I direct the witness not to answer. What do you mean "decision-making process"? Try to drive a car or not to drive a car? You need more direction on that question.

Q. You don't understand that question now?

MR. KEARNEY: What decision-making process are you talking about?

Q. Do you understand the question, sir?

A. Not completely.

MR. KEARNEY: Not an answerable question mark.

MR. EDELL: I won't quibble with you, Mr. Kearney.

Q. Did Dr. Mold's lack of any formal education with respect to biochemistry suggest to you that he was not competent to evaluate the work that was being done for Ligget by ADL?

MR. SIRRIDGE: I want to object to the form of the question. I don't know where biochemistry came from.

A. My understanding -- and you have to understand that the way the case was run at Arthur D. Little it was largely contact between Mold and Kensler.

Q. You had contact with Dr. Mold.

A. I had contact with Dr. Mold generally in wondering whether we were in fact satisfying his requirements as a manager of the system, and on a few specific cases like some of these additive things where he was my direct contact. But with respect to the decision-making process, I was not part of that interface, so I can't answer that.

Q. I misspoke before. What you indicated was that he was very competent within the area of chemistry, correct?

A. He was competent as a chemist. And from what I could see of his management of the research

program overall, it seemed to be organized and well run.

Q. But he didn't have any formal training, to your knowledge, in biology?

A. Yes. And again sort of retrospectively my sense is that a lot of the important biological decisions were in fact Kensler's, and I think that Mold trusted him with that.

Q. What do you base that on?

A. Based on the fact that I think that Mold understood that he was not a biologist, number one. And, number two, that Kensler had a lifelong experience in this area and, in fact, was perhaps the best person to make those decisions. But that is a supposition on my part. That's how it looked to me from the outside.

Q. In your discussions with Dr. Mold, did you ever discuss bio-assay results?

A. No.

Q. Did you ever discuss chemistry?

A. The only chemistry we talked about was the chemistry of the additives, as a matter of fact, and what the relationship of the chemistry was to the things we found in the literature.

Q. You didn't discuss the mutagenicity tests with him at all?

A. Most of those were done after he left.

Q. Did you ever have discussions with him regarding the marketing of the palladium cigarettes?

A. No.

Q. Were you ever furnished with any information concerning what Dr. Mold said in testimony in this case concerning the marketing of the palladium cigarettes?

A. No.

Q. In your discussions with Mr. Kearney or representatives of his firm, they never told you what Dr. Mold said with respect to the decision not to market the palladium cigarettes?

A. Not specifically.

Q. Generally did they make any comments in that regard?

A. There were some comments made, that based on the conversations that were made, that Dr. Mold's position after he retired was rather different and possibly opposite to what his position was when he worked for the company.

Q. They made that statement?

A. No, that was my presumption based on what my understanding was of Mold's enthusiasm about and his commitment to the work that was being done and --

Q. Was it your understanding that Dr. Mold didn't think that there was merit in the palladium cigarette while he was employed by Ligget & Meyers?

MR. KEARNEY: Object to the form of the question.

(Question read.)

MR. EDELL: Would you answer the question?

A. No.

Q. What was your understanding as to Dr. Mold's evaluation of the palladium additive cigarette while he was at Ligget & Meyers?

MR. KEARNEY: What is his understanding now?

Q. What was his understanding while he was at ADL as to Dr. Mold's evaluation of the palladium additive cigarette?

MR. KEARNEY: If he had an understanding.

MR. EDELL: If he had no understanding, he would say "I have no

understanding."

A. I didn't know what his understanding was about marketing. I did know that he was enthusiastic about the research program, and he acted as if he was behind it and in pursuit of it.

Q. When you say enthusiastic about the research program, was he enthusiastic about the results of the research program, to your knowledge?

A. Yes, and the prosecution of it.

Q. With respect to the palladium additive cigarette, correct, you are nodding your head?

A. Yes, that's my understanding.

Q. It is your understanding from your conversations with Mr. Kearney or Mr. Decker, someone from their firm, after he left Ligget & Meyers' employ, that he no longer was enthusiastic about the Ligget & Meyers' cigarette, is that what you meant?

A. No, that wasn't what I meant. No. His attitude to the way he was doing his work, or his recollection of it, seemed to be different than my recollection of his enthusiasm for it at the time.

Q. In what way, sir?

A. There seemed to be a bitterness that he had not been properly treated by Ligget, that they had

not allowed him to publish. And that didn't fit with what I knew was Jim Mold.

Q. In other words, he was professional and enthusiastic about his work while he was there and the work that was being done by Arthur D. Little?

A. That is correct.

Q. And he didn't badmouth Ligget & Meyers during the contact that you had with him, is that correct?

A. Absolutely.

Q. But his position on the viability if the palladium additive cigarette never changed, to your knowledge?

MR. KEARNEY: I object to the form of the question. There is no testimony at all that this witness knows what Mold's view of the viability of program was either then or now.

Q. Did you ever discuss that with Dr. Mold?

A. No.

Q. What is coumarin?

A. coumarin is a volatile material that is used as a flavoring component. Coumarin itself is not used anymore as a matter of fact.

Q. Did you have discussions with Dr. Mold

with respect to coumarin?

A. Yes.

Q. In what regard?

A. We were looking at a whole class of chemicals. In fact we did some biological tests on them. I don't know -- we had a confidential agreement with Ligget on the substance of that work.

MR. KEARNEY: Why don't we take a break now. See what our position will be.

(Short recess.)

MR. EDELL: ADL, after you returned in 1974, after you became manager of the Life Sciences section of ADL, we were talking about conversations in other related matters with Dr. Mold, and you came up with your confidentiality dilemma. And we are going to resolve it how, Mr. Kearney?

MR. KEARNEY: You are going to ask him questions and the witness is going to answer.

MR. EDELL: I thought you were going to discuss the confidentiality issue.

MR. KEARNEY: Put the question and he'll answer.

Q. Did you have a any discussions, conversations, with Dr. Mold?

A. Yes.

Q. What were those conversations?

A. Dr. Mold asked Arthur D. Little to prepare some literature of views looking at the technology relating to coumarin and several very closely related materials to coumarin.

Q. Is this the class of chemicals you just referred to?

A. Yes.

Q. Was that work that was done in conjunction with the palladium project?

A. I don't know what connection it had to the palladium project. This was an independent question that he raised with us. I don't know what the connection was.

Q. What other additives were being tested at Arthur D. Little for Ligget & Meyers?

MR. SIRRIDGE: Object to the form of the question.

MR. KEARNEY: Object to the form of the question.

A. The additives that were looked at by

Arthur D. Little were two or three coumarin derivatives. He never looked at coumarin.

Q. I apologize for the question because it was unclear and their objection is well taken now that I hear your response.

Other than palladium were there any additional additives that you looked at with respect to analyzing smoke condensate?

MR. SIRRIDGE: Objection to the form of the question.

A. No.

MR. EDELL: What was wrong with that?

MR. KEARNEY: Let's go.

MR. EDELL: I want to know. Maybe I should ask the question again.

Q. Didn't you say smoke condensate with respect to the palladium additives?

A. The mutation, but it has no connection to the coumarin.

Q. That is why I restated my question with respect to the smoke condensate. We could have been talking about flavorings or something else. And I was talking about something that was attempting to reduce

the carcinogenicity of the smoke condensate. Do you understand that?

A. I understand.

MR. SIRRIDGE: I'll object, my form objection.

Q. Between the years '74 and, let's say, '80 what other type of work did you do for Arthur -- I'm sorry -- what other work at Arthur D. Little did you do for Ligget & Meyers?

A. I did personally none.

Q. What other work was being performed in the Life Sciences division of Arthur D. Little for Ligget & Meyers?

A. The major part was in this two-year inhalation study that we were running. This was a very large program.

Q. Specifically what years were they?

A. I really don't remember, I think it started late '70s and ran on to early '80s, but I just honestly don't remember.

Q. Was Ligget a significant corporate client for the Life Sciences division for Arthur D. Little?

MR. KEARNEY: When?

MR. EDELL: '74 to '80.

A. Ligget was never that dominant, but during the years that I was there, Ligget went from a reasonable contributor to our income to zero.

Q. This is of your corporate clients, is that correct?

A. Of my total client base.

Q. I'm not talking about total client base. I'm not talking about NCI or NIH. I'm talking about commercial clients. Were they a significant commercial client, not for you personally, but Life Sciences division of Arthur D. Little from year '74 to '80?

A. What do you mean "significant"?

Q. More than 5 percent.

A. My recollection is that when I first started there, that they were providing of the commercial side perhaps 20, 25 percent of the total revenue. And it went down almost every year after that until the early '80s when it completely disappeared. It was never a dominant or we'd have been hurt if the money weren't there, but --

Q. What other tobacco company, if any, did Life Sciences department do any work for?

A. There are two that I could recall.

Q. They are?

A. One was with Brown & Williamson and the other was with R.J. Reynolds.

Q. What work was performed for Brown & Williamson and when?

MR. KEARNEY: At this juncture we do have some problem. I have been advised that the work that was done for Brown & Williamson was under a confidentiality agreement and that the doctor is not in a position to talk about it. In addition -- well, that's all.

Q. Was there a standard confidentiality agreement with all of the corporate clients?

A. There was at least a standard confidentiality agreement. With many of them we embarked on fairly rigorous and stringent confidentiality agreements that had restrictions over and above the standard boilerplate that we usually had. As a matter of fact, my recollection was that the R.J. Reynolds one was -- you legal guys would have had a ball with that one -- I never quite understood, but it put enormous constraints on the way we were able to handle information.

MR. KEARNEY: Could we go off the

record.

(Discussion off the record.)

Q. You told us that during the years '74 through '89, sometime during that time frame, the Life Sciences division of Arthur D. Little did work for Brown & Williamson and R.J. Reynolds, is that correct?

A. We proposed work for Brown & Williamson. We negotiated a protocol. We were very close to doing it. And then for reasons that were never clear to me Brown & Williamson said they didn't want to do it. So while we prepared a protocol, we said they wanted to do something. But for reasons from them, they said they were not going to proceed. So we didn't do anything for Brown & Williamson except write a protocol. We were within two weeks of ordering the animals and they said no.

Q. Was it some type of bio-assay?

MR. SIRRIDGE: Objection.

Q. You didn't do any work for them?

A. We didn't actually do any hands-on work. What we did was we designed them a very good protocol.

Q. Who did you work with at Brown & Williamson?

A. I can see him but I can't remember his

name. I'm sorry, I don't remember his name.

Q. During what period of time did you prepare the protocol?

A. Early '80s. Early to mid-'80s, maybe '83.

Q. Who gave you the instruction not to go further than the protocol?

A. The person that was my contact at Brown & Williamson.

Q. Was that person a lawyer or person who was assigned?

A. I think he was a product engineer. He had responsibility over this area.

Q. When you say "this area," you are referring to what?

MR. KEARNEY: Well, we're not going to talk about the substance.

Q. Who was responsible for preparing the protocol?

A. The protocol was written largely by me and one of my associates by the name of Mark Goldman.

Q. Where is Mr. Goldman?

A. Mr. Goldman is now with an organization called Anderson Testing Laboratories somewhere in the

suburbs of Boston. He and his boss left to set up a small company of their own.

Q. And if you were to go back to Arthur D. Little and try to locate that protocol, what would you do?

A. See if I could go back to the original case file, really proposal files because we never signed a contract -- the proposal file and see if it was there.

Q. How long does Arthur D. Little keep proposal files?

A. I have no idea.

Q. You wouldn't go searching through all the records of Arthur D. Little itself?

A. No. I'd ask my secretary to see somewhere in the computer if the identification number was there and to get somebody to the warehouse and see if it was there.

Q. What identification number would you give?

A. Every proposal that comes in gets an identification number. Every client contact we make when we have one gets a proposal number. And when you sign a contract gets a case -- a new number.

Q. Where are those numbers maintained?

A. Central corporate files of the company.

Q. What other information are contained in the central corporate files of the company?

A. I haven't the foggiest idea.

Q. With regard to the work with respect to Brown & Williamson, did you have any contact with anyone other than this scientist type product engineer?

A. There were several people who were advisory, and there were other people from Brown & Williamson who were in that group.

Q. Do you recall whether there were any lawyers involved in any of these discussions?

A. I'm sure there were, but I don't remember them.

Q. Was it the practice when you met with a potential client to prepare a memorandum with respect to that which transpired between you and the client or prospective client?

A. Not necessarily.

Q. Under what circumstances would you prepare a memo?

A. What was usually prepared was what we

call the lead report which would identify the client, the company name, who we contacted, a brief statement of what the contact was, and what the followup was going to be. And that went into the system.

Q. With respect to the R.J. Reynolds, when did you do work for R.J. Reynolds?

A. That was middle '80s.

Q. Who was your contact at R.J. Reynolds?

A. A whole army of people, Wally Hayes and Chris Coggins, I guess, were the two chief people.

Q. Were they scientists?

A. Wally Hayes is chief toxicologist and Chris Coggins is chief inhalation toxicologist.

Q. You actually did work for them?

A. We did a single study for them to sort of -- they were in the process of building a new lab and they needed some work done fairly quickly. And we put together a program for them to do a single study to develop some information until they got their own act together down in Winston-Salem.

Q. With respect to the work done for Ligget & Meyers was there a confidentiality agreement?

A. Yes.

Q. Did that agreement speak to in any way as

to the publication of the results of your studies?

A. Speak to the issue of?

Q. Publication of the results of your studies.

A. I don't know whether it did, but there are several -- a good number of studies that were published out of Ligget & Meyers work from Arthur D. Little in the peer review literature.

Q. I understand that. What does the standard confidentiality agreement say with respect to publication of the results of the studies of the work being performed for a corporate client?

MR. KEARNEY: I object to the form of question. It assumes there was a standard.

MR. EDELL: I thought he said there is a boilerplate.

A. I don't recall whether what we call a standard confidentiality agreement addressed this. My recollection is it did not. And if we thought we were going to publish something out of the work, that that was probably an added clause or something to the confidentiality agreement. But that is my recollection.

Q. Do you know whether there was any

constraints on Arthur D. Little with respect to publication of the results of the work performed for Ligget & Meyers?

A. I don't know that.

Q. Who would know that?

A. Kensler probably.

Q. And if we wanted to ascertain whether there was a contract between them which spoke to the issue of publication, what would we ask for and where would we go to locate it? Would that be in the corporate file?

A. The contract certainly would be.

Q. And what about the contract? Does that normally contain the confidentiality agreement also, or was it a separate document usually?

A. I've seen it both ways. I guess it would depend on the individual agreement, the way it was worked out, whether the lawyers wanted the confidentiality agreement in the contract or whether it was just an appendage to it.

Q. In either event would it be part of the corporate file?

A. I don't know. I would guess so.

Q. You don't know what the normal practice

was in the Life Sciences division of Arthur D. Little with respect to maintaining those when you were the manager for 10 years?

MR. KEARNEY: Objection to the form of the question. It is argumentative and unnecessarily argumentative.

A. Rephrase it.

Q. Do you have any idea whether or not in the corporate files there would be a copy of the contract and the confidentiality agreement?

A. I don't know what documents are kept in the Arthur D. Little contracting corporate file.

Q. Is there any other type of corporate file other than the contracting corporate file?

A. That's what you asked me as to -- you are asking me where would the contract be, and I'm saying it would be in the corporate contracting file.

Q. In other words, is there a general corporate file for the various corporate clients that Arthur D. Little has in the Life Sciences division, or is it only a copy of the contract and this lead report that you alluded to before?

A. The central total contracting file for the company is kept separately. I guess Life Sciences

kept a copy of the contract. I have no idea where that file is. Also I have no idea what the retention time is.

Q. Did Arthur D. Little do any work for any law firm representing any tobacco company?

A. Yes.

Q. What law firm?

A. Webster & Sheffield.

Q. When was that work performed?

A. I don't know exactly because I was not the central contact on that. Kensler was the case leader. And what I do remember saying on the case status reports that I would get was that Webster & Sheffield was the client.

Q. What was the nature of that work?

A. I don't know.

Q. When did that work occur.

MR. KEARNEY: If you know.

MR. EDELL: If he doesn't know, he can't answer the question.

A. It was episodically over the 10 years I was there, I saw it with some frequency. But I can't pin down how many times or what the time intervals were. I can't remember.

Q. If we wanted to locate all the work that was done by Arthur K. Little for the Webster & Sheffield firm, how would we locate it?

A. If there are any files, they are in a warehouse somewhere that are identified by Webster & Sheffield as the client, if they still exist, if the files still exist.

Q. And you don't know what the document retention program was?

A. Arthur D. Little is a very eclectic organization, and unless rules have changed, the document retention policy was largely, at least for case work kind of things, was largely the decision of the case leader if they thought it was of corporate importance that they keep it around. If it was not necessary they would empty their files. It might have changed, but that is how it was some years ago.

Q. What was the nature of the work Arthur D. Little did for Webster & Sheffield?

MR. KEARNEY: Asked and answered.

Q. Any other law firm other than Webster & Sheffield for whom Arthur D. Little did work?

A. Yes. I did work for a law firm in Milwaukee, again whose name I don't remember. And it

had to do with writing a health effects document on a fluorescent additive that they add to bowling alley dressings.

Q. I should have restricted it, at least in the first instance, to law firms representing tobacco companies, cigarette companies.

A. No.

Q. To your recollection, there was no other work performed by Arthur D. Little for a law firm representing a tobacco company. Is that correct?

A. Not to my knowledge.

Q. When I say "tobacco company," you understand that to be a cigarette manufacturer?

A. Yes.

Q. For what period of time was Ligget & Meyers responsible for approximately 25 percent of the corporate revenues of the Life Sciences division of Arthur D. Little?

MR. SIRRIDGE: Object to the form of question.

MR. KEARNEY: Object to the form of the question.

A. I don't exactly recall the time. But it was until that two year chronic inhalation study

finally got reported out.

Q. Sometime in the early '80s?

A. I would think so. And that was really the end of the major input from Ligget & Meyers. After that it really dropped off because that was such a big program.

Q. Did Arthur D. Little, again with respect to the Life Sciences division, have a corporate client which accounted for a greater percentage of its yearly revenues, let's say, up to 1980 other than -- greater than Ligget & Meyers?

A. A single corporate client?

Q. Yes, sir.

MR. KEARNEY: I object to the form of the question. Do you mean Life Sciences division revenue?

MR. EDELL: Yes. I thought I made that clear.

MR. KEARNEY: Now you said, "Arthur D. Little with respect to Life Sciences, did they have a client larger than 25 percent?" I don't know whether this refers to Life Sciences or Arthur D. Little.

MR. EDELL: I was referring to Life

Sciences.

A. My recollection whether there was anybody larger, there may have been. I guess what I can say is that Ligget & Meyers in the pre-1980, pre-1979 was one. Larger corporate clients in Life Sciences for Arthur D. Little.

Q. Not only for a particular year but for a continuum of years, is that correct?

A. I would say between '74 and '79 they were one of the larger contributions for revenues.

Q. You are aware that Arthur D. Little was a significant -- or accounted for a significant amount of Life Sciences division revenues dating back into the '50s, isn't that correct?

MR. KEARNEY: Object to the form of that question.

A. I don't know what the contributions were because I wasn't party to those numbers until I became an officer of that company.

Q. You left Arthur D. Little in 1989?

A. That is correct.

Q. To go with the Health Effects Institute?

A. Yes, sir.

Q. And your responsibility at the Health

Effects Institute are what?

A. I'm the president and chief executive officer of Health Effects Institute, and I'm the executive director and chief executive officer of Health Effects Institute asbestos research.

Q. You don't do any research, do you?

A. No.

Q. You don't write any papers on the health effects of asbestos?

A. I've got an expert committee who is in the late stages of doing that, and I have edited and worked with them on it. I am not the author of it, but I have been working on it.

Q. You are not one of the experts on the committee, are you, sir?

A. No, I am not.

Q. Basically you are responsible for more administrative type work?

A. No. I rather think that I applied some rather cogent scientific questions that made them think a little about what their answers are. And I made some editorial work to clarify some scientific issues.

Q. But insofar as the -- let me back up a

little bit. Maybe I'm presupposing something that is not correct. What does the Health Effects Institute do?

A. The Health Effects institute is a nonprofit corporation. It is jointly funded by the Environmental Protection Agency and the 27 companies who make and sell motor vehicles, engines in this country. And they each put into our pot dollar for dollar money that we then transmit to universities throughout the world in supporting research relating to the legal effects of motor vehicle emissions.

Q. So the expert committee passes on grants, is that correct?

A. That's correct.

Q. And you don't get involved in that grant process?

A. Yes, I do.

Q. You do in what way?

A. Especially in the area of environmental health, having spent 30 years in the business, I think I have some cogent technical things to offer. So I actively participate in the grant review process and in the award process.

Q. What exactly is your role in the grant

review process?

A. I make individual commentary on the strengths and weaknesses of various grants. And I make those known when the grants are being discussed by the research committee.

Q. Before I forget, Arthur D. Little has other divisions other than the Life Sciences division, is that correct?

A. Many.

Q. Did they have any divisions that were dealing with warnings and what warnings a corporate client might want to place on its products?

MR. KEARNEY: I have to object to this question. Now we're getting to the point where I permitted extreme latitude in terms of relevance. What -- if you tell me what the relevance of that question is to this witness' opinion about which this deposition is supposed to be taken, I may consider letting him answer it. But this is going entirely too far afield. What is the relevance to that of that question to this witness' testimony?

MR. EDELL: His particular testimony in this case?

MR. KEARNEY: To his testimony, exactly.

MR. EDELL: Probably very little.

MR. KEARNEY: Why don't we just skip it and go on to something else.

MR. EDELL: Consider it done.

Q. Getting back to the Health Effects Institute, there is the Health Effects Institute asbestos research?

A. Yes, it's a completely separate nonprofit corporation.

Q. How is that set up?

A. It's set up the same way government private sector funding. PA contributes half. The private sector in that regard are the former manufacturers, real estate interests, which includes a whole passel of people all the way from mortgage bankers to shopping mall operators and the insurance sector.

Q. This relates to the asbestos property damage claims?

A. No. This relates to an assessment of knowing or trying to find out what the asbestos levels are in public buildings, what the health consequences

of that might be, and what makes sense for rational abatement techniques given that information we have.

Q. Does the institute make recommendations with respect to what steps should be taken?

A. The institute, when our report is complete sometime, I hope, by the end of March will have as part of its report suggestions and recommendations for strategies for dealing with asbestos in public buildings. And that will be sort of the consensus viewpoint of this panel of 14 or 15 people which we have drawn together to prepare the report.

Q. Does the Health Effects Institute solicit funding from any other source other than the 27 vehicle manufacturers or component manufacturers of vehicles?

MR. KEARNEY: I object to the form of the question.

Q. Do you understand the question?

A. I do indeed. It's very close to my heart. Our institute has had stable funding of $6 million for the last 10 years, which means that my research budget is in fact down by 30 percent in real dollars. I have been working with the petroleum

industry to see if I could encourage them to become sponsors of the institute. That is in its early stages, but they seem interested.

Q. Anyone else that you have approached, any other industry?

A. Not on the -- well, we do have another small wheel that is going on on the outside. We are doing an epidemiology study program that we are doing at the behest of the Environmental Protection Agency. And we got six industrial trade associations to buy in as partners to do that. And they each put in a flat amount so that they would be participants and could be, sort of be, partners in this study group we were making.

Q. What trade associations are included in this group of six?

A. Engine Manufacturers Association, Motor Vehicles Manufacturers Association, Chemical Manufacturers Association, American Petroleum Institute, the Gas Research Institute. I'm missing one which will have to remain nameless. And then EPA is the other participant.

And what we're doing is we have brought together four study committees to write papers on

critical issues in environmental epidemiology. And sometime this fall we'll have a public meeting telling people about it. And then we'll publish it in the literature.

Q. Have you ever done any epidemiological work yourself?

A. Not hands on epidemiology, I have looked at an awful lot of epidemiology data and especially relating to coffee consumption and cancer. I have presented a paper last year at the Risk Assessment Association. And I'm working on a paper right now analyzing the epidemiology data relating to cancer and coffee consumption. It was the Society for Risk Analysis. The paper was prepared in October in New Orleans.

Q. Has it be published?

A. It's an abstract extract.

Q. Has it been submitted for publication?

A. No. It's listed in my list of publications.

Q. Have you ever participated in the design of an epidemiological study?

A. I think that I've contributed to helping people think about it. I wouldn't go so far as saying

contributed to the design of one. But I've commented on them. I've helped, I think, some of our investigators understand how to put their experiments together a little bit better. But I wouldn't say I contributed to the design of it in that sense of having formulated the design of the study.

Q. Prior to your participating as an expert in this case, have you ever familiarized yourself with the epidemiological literature with respect to cigarette smoking and good health?

A. Not in great depth. I have understood and read the Surgeon General's Reports over the years.

Q. Cover to cover?

A. No.

Q. Generally you are familiar with the Surgeon General's Reports?

A. I'm familiar with the substance of them, of the key findings.

Q. Did you actually review the epidemiological studies that formed the basis for the various Surgeon General Reports?

A. Yes.

Q. When did you review them?

A. Oh, several types over the last 10 years.

Q. And in what regard -- why would you go and review the epidemiological studies that serve as the basis for the Surgeon General's Reports on smoking and health over the last 10 years?

A. I think it's one of the most important public health documents that possibly have ever been prepared. And I think the people in environmental health sciences, it's interesting to see how these people came to that conclusion. My interest earlier on was academic. My interest recently is to understand them better with respect to some views that I hold with respect to occurrence of cancer and the role of cessation of smoking.

Q. So I'm clear, is it your testimony that you reviewed the Surgeon General's Reports during the last 10 years, or that you actually reviewed the epidemiological studies that are cited in those reports?

A. I didn't mean to indicate that I reviewed -- I reviewed the reviews as cited in the Surgeon General's Report.

Q. But you didn't?

A. I didn't go back to the first literature on that, no.

Q. Are there any other papers that you have ever published which related in any way to interpretation or evaluation of epidemiological study other than the caffeine study?

A. I guess one of the other things that we did at ADL was we prepared some rather extensive monographs on surfactants that are located in detergent products for the Soap and Detergent Association. We had to evaluate all the human data we could. I had to look at it and write a conclusion what I thought that human data meant.

Q. It was your job to evaluate what the epidemiological data was with respect to surfactants?

A. Yes, I wrote what I thought that meant with respect to surfactants.

Q. Was that ever published?

A. Yes.

Q. Where was it published? Can you look at your list of publications?

A. There were several numbers.

Q. It's Sivak 2, I do have it. Is that the bibliography?

A. Of my publications, right. No. 140.

Q. Okay, 140.

A. 139, 107. And 101. Which, I'm sorry, has a misspelling in it. Its fragrance, and that one you'll not be able to read because it's a translation into Japanese of one we did in English. And the only English words there are the names of authors.

Q. Again these are not epidemiological studies but they are papers that relate in some way of evaluation of the epidemiology?

A. Among other things, we looked at a whole range of things, environmental safety, acute hazards, and epidemiology, and these are rather global pieces, but epidemiology studies with respect to the human studies was part of the evaluation.

Q. Do you believe you are qualified to evaluate epidemiological studies to determine whether or not they are done correctly or incorrectly?

A. To some degree. I think that where I have questions with respect to some of the details of that, I have sought out counsel and assistance of card-carrying epidemiologists, if you will.

Q. Let's assume you wanted to construct an epidemiological study with respect to cigarette smoking and lung cancer. Tell us how you would do that.

A. There are several ways one could go about it. One could use sort of a Wynder model of a case control study of trying to make contact with hospitals and places that have surgical records for lung cancer, determine what the exposure histories of those people were, get concurrent controls for those people, match them for age, sex, social background, all the things one needs to know.

Q. Tell me what all those items are that you would want to match them for.

A. Age, sex, social background.

Q. What does that mean?

A. Income status, occupation. The most important thing would be to try to sort out with respect to the exposure what the confounding variables might be.

Q. And what would those confounding variables be with respect to an epidemiological study on cigarette smoking and lung cancer?

A. They would be an understanding of all of the other environmental agents that could contribute an influence to the outcome.

Q. I'm listening. What are they?

A. Among others, radon, does the person live

in an urban or rural environment, what is the air pollution in the area, hormonal status -- in tumors some lung tumors do have some hormonal dependence -- and making sure you got the smoking history right.

Q. Who is Dr. Wynder?

A. Dr. Ernest Wynder is the head of the American Health Foundation, epidemiologist by training, physician. He has published extensively in the area of smoking and health for years.

Q. Have you ever formulated an opinion with respect to his qualifications?

A. Yes.

Q. And what is that opinion?

A. He's a very inventive and creative epidemiologist. He's the author of some of the early seminal publications in this area, both in epidemiology and that first skin painting paper which he did which was not an epidemiology study but was an experimental study.

Q. A well-respected epidemiologist?

A. Yes.

Q. One of the leading epidemiologists in the area of cigarette smoking and health?

A. He's prominent.

Q. Who would be the leading epidemiologist on cigarette smoking and health?

MR. KEARNEY: Object to the form of question.

MR. EDELL: What is the objection? You don't know what leading is?

MR. KEARNEY: No. It assumes there is one who is the leading epidemiologist. So when you have an assumption there is an objection to form.

MR. EDELL: Thank you.

Q. Can you name some of the leading epidemiologists in the area of cigarette smoking and health?

A. I think it's generally accepted that the seminal study, if you had to pick one study, is the Doll & Peto study of British physicians. That has got to be one of the real landmark studies with respect to smoking and lung cancer.

Q. Would you consider Dr. Doll, Sir Richard Doll --

A. Yes.

Q. -- to be one of the leading epidemiologists in the world?

A. That he's one I could honestly say.

Q. Would you say he's the leading epidemiologist?

A. I think that is impossible to say, who the leading epidemiologist is.

Q. I don't mean this in any derogatory manner. But relative to you, would you defer to Dr. Doll on the interpretation of epidemiological studies with respect to cigarette smoking and health?

A. I certainly would.

Q. We have Doll & Peto as the seminal epidemiological study. Are there other leading epidemiologists in addition to Doll and Peto?

A. In the smoking area?

Q. Yes, smoking and health area.

A. I suspect there are, but I can't put my fingers on those names right now.

Q. Are you familiar with any other epidemiological studies other than the Wynder study and the Doll & Peto study in the area of cigarette smoking and health?

A. Not specifically by citation and name that I can give you right now.

Q. At some point in time would you have

considered Dr. Wynder to have been a leading epidemiologist in the area of cigarette smoking and health? In other words, he may not currently be one of leaders. But at some point in time would you have considered him to have been?

A. Yes.

Q. When was that?

A. I'm not sure that he's not right now among the leading. You asked me whether he was the leading.

Q. With respect to Dr. Wynder, would you consider him to be a leading epidemiologist in the area of cigarette smoking and health?

A. Yes.

Q. Would you defer to him on the evaluation of epidemiological studies with respect to cigarette smoking and health?

A. Less so than to Doll. I like to have my epidemiologist along when I talk to Ernie.

Q. With respect to you -- just you, forget about having your own epidemiologist along. Is it fair to say that Dr. Wynder's expertise with regard to epidemiology is much greater than yours?

A. Yes, that is fair.

Q. Now, on your CV you indicate that you have completed several extensive literature surveys evaluating commercially important classes of chemicals, whether for their environmental acceptability and human safety. What commercially important classes of chemicals have you done that for?

A. The most important was the soap and detergent that was done three separate times over 12 years. And then there were other single evaluations that were done.

Q. And what did those involve?

A. Again it was commercially important to the bowling alley industry, this fluorescent dye issue.

Q. It was done in conjunction with a legal case, though, correct?

A. I guess ultimately the question came from the attorney representing the trade association, and asked me to do it. The use of my product, as I was told, was to give them some counsel as to whether there were any problems out there. Whether it was used in the legal setting, I have no idea. The other place where I have written documents is related to work that we did relating to the siting of solid waste

incinerators.

Q. What do you mean, "the siting"?

A. When people plan to put in a new garbage burning facility, there is always an argument about where it's going to be, not in my back yard. So these adjudications generally come before some administrative body, state health body, or some body. And Arthur D. Little was hired on several occasions to prepare complete engineering and health and environmental assessments of these citings. And my responsibility was for the health effects side effects.

Q. And were those literature surveys that you performed published?

MR. KEARNEY: Objection to the form.

Q. With respect to solid waste incinerators.

MR. KEARNEY: I object to the form of the question.

A. They were not published in the peer review literature. They were submitted as support documents to the various clients that we worked for. And then they were presented and defended at the public hearings.

Q. Who were the client's that you represented with respect to the solid waste incinerators?

A. There were several county and municipal organizations, one in Maryland, one in New York, one in Massachusetts. And then we represented an insurance company in Maine who wasn't happy that an incinerator was going to go up rather close to them.

Q. You also indicate in your CV, which is again marked P-1, that you have appeared as an expert witness in various legal and administrative proceedings concerned with environmental health issues.

A. This is what I'm talking about, the hearings that were related to the siting of these garbage-burning places.

Q. Have you ever acted as an expert in any case involving evaluating the etiology of a person's cancer?

A. I have never appeared as an expert -- these were not expert witnessing cases. These were all administrative proceedings. I have never appeared as an expert witness except for once a long time ago before the Supreme Court of Canada, but never in

relation to what you say.

Q. So you've never been called upon to form an opinion with respect to the etiology of any individual's cancer?

A. Not as an expert witness.

Q. Have you ever been called on in a professional capacity with respect to patients with cancer?

A. No.

Q. Have you ever treated a patient with cancer?

A. I have not.

Q. Have you ever participated on a team of professionals to evaluate what particular medication should be used in the treatment of a patient's cancer?

A. No.

Q. Have you professional capacity to evaluate any individual's cancer -- Is it fair to say then that you are not qualified to formulate a scientific opinion with respect to the cause of a particular individual's cancer?

A. That is not true.

Q. You believe that you are qualified to make a determination as to the cause of a particular

individual's cancer?

A. No. I don't think anybody in the world is qualified to make that statement.

Q. Why?

A. The process of carcinogenesis, I think, is complex. And there are enough unkowns in the piece now to say that we know with scientific certainty that a certain exposure is directly the cause of a serious cancer. I don't think there is anybody in the world that has that kind of omniscience or knowledge of the process to make that statement.

Q. Let me ask you this: Do you think you have the expertise to formulate an opinion as to whether more probably than not a person's cancer was due to a particular exposure, if you will?

A. Not for a single person, an individual person.

Q. You mentioned that you acted as a witness sometime ago in Canada, is that correct?

A. Yes.

Q. And that was in conjunction with what?

A. That was in conjunction with a patent trial when I was Biodynamics. I was hired to do some microbiological biochemical work relating to the

formation of an antibiotic from a microorganisms. And I was called in the Canadian Supreme Court to give the evidence that I did in connection with this patent litigation.

Q. That's the only other legal matter that you have acted in as an expert witness?

A. As in a trial?

Q. In any capacity, have you ever acted as a consultant in a litigation matter, not that you actually participated in a trial or rendered a formal report or were named as an expert, but they hired you as an expert to give consultancy for a litigation?

A. A number of years ago, I don't remember exactly, I did prepare for Webster & Sheffield --

MR. KEARNEY: Wait.

(Discussion off the record.)

MR. KEARNEY: I'm not going to let him answer it.

Q. The work that you did for Mr. Kearney's firm that Mr. Kearney will not allow us to inquiry into about, when was that done?

A. Early '80s.

Q. And to your knowledge, was that work performed with respect to a certain piece of

litigation?

A. I don't recall.

Q. Did you prepare any written document?

A. I think I worked on a written document. I don't remember I ever sent anything.

Q. You evaluated documents?

MR. KEARNEY: I object to the question.

A. Yes.

MR. KEARNEY: And I direct the witness not to answer. I'm asserting the privilege over this area of questioning. You can inquire into when and who he had contact with, but not the substance of the consultation as it is covered by the work product privilege. And I don't want to risk waiving that.

MR. EDELL: You indicated I could inquire as to the individual with whom he was working at the firm.

MR. KEARNEY: Yes, so make sure you let me interpose my objection before you answer in that area. Go ahead, Marc.

Q. Who was your contact at Webster & Sheffield?

A. Mr. Decker and Mr. Kearney.

Q. Did you work with any other expert?

MR. KEARNEY: Objection.

MR. EDELL: Why is that an objection?

MR. KEARNEY: Because it may get into the substance of the work pertaining to which I'm asserting the privilege. Are you going to ask a litany of leading questions?

MR. EDELL: I'm not going to ask the substance of what was done.

MR. KEARNEY: You can ask the question "Was anyone else there?"

Q. Did anybody else participate in the work that you were doing other than Mr. Kearney and Mr. Decker?

A. I don't understand.

Q. Participate, work on, work together, communicate with.

A. I was the sole source of the work that I did for Mr. Kearney and Decker.

Q. In other words, there wasn't another expert who was working in conjunction with you?

A. That is correct.

Q. And you weren't working in conjunction with another expert?

A. That's true.

Q. Did you communicate in writing with Mr. Kearney with respect to this project?

MR. KEARNEY: Asked and answered but I'll let him answer it again.

MR. EDELL: I thought he said he was working on reviewing something but --

A. I thought I had said that I thought I had worked on some documents but I was not sure that I had ever sent them.

Q. Do you still have them?

A. No.

Q. Do you know what happened to them?

A. No.

Q. Who would know?

A. It's unlikely that they exist anymore.

Q. Were you ever given any direction with respect to retaining those documents or destroying those documents?

A. No.

Q. If you had sent them to Mr. Kearney, or Mr. Decker, or anyone here, would you have kept a

record of that?

A. There may have been a cover letter. But when I left Arthur D. Little, I cleaned out most of my files except those things that I thought were really necessary for the business of the company. And it's unlikely I would have kept that.

Q. On your resume it states you have served on national review committees for the National Cancer Institute.

A. That's correct.

Q. Did any of those review committees relate to epidemiological work?

A. One of them was a study section that looked at research programs related to anticarcinogens, materials in the diet that could prevent carcinogenesis. And as part of this review body, we did review some epidemiological studies that were submitted to the board for review.

Q. You are a member of the American College of Toxicology?

A. That is correct.

Q. What are the requirements for joining that organization?

A. The American College of Toxicology is a

professional society of toxicologists. The requirements for membership is that you be nominated by two other members and that you present a reasonable publication record to indicate you are competent in the field.

Q. Is there any tests that you have to pass?

A. No.

Q. Any minimum educational requirement?

A. Not in writing, but certainly de facto Ph.D.

Q. It says you are a member of the American Association for the Advancement of Science?

A. That's right.

Q. And what is the membership requirement for that organization?

A. I'm not sure. I have been a member for 30 some years. I think that you can probably become a member if you want to and pay the dues.

Q. No educational requirements, no experience?

A. I don't know for sure. But my recollection is if there is, it's not a stringent one.

Q. American Association for Cancer Research.

A. That's like the American College of

Toxicology. That requires nomination. There the selection process by the membership committee is pretty rigorous.

Q. What criteria do they use?

A. Again, demonstrated competence in the field as shown by peer review publications and recommendations from your peers.

Q. The American Society for Cell Biology?

A. Yes.

Q. What are the membership requirements there?

A. There is again a nomination by other members and demonstrate that you have capability in the field from your publication record.

Q. Environment Mutagen Society.

A. It's nomination, I forget now how rigorous the selection process is on that. I think it's somewhat less than, say, Cell Biology or Cancer Research Society.

Q. society for Risk Analysis and Society for Toxicology, two separate entities?

A. Yes.

Q. Society for Risk Analysis, what is the requirement?

A. Nomination by two members and demonstration of capability in the area.

Q. What is the Society for Risk Analysis? What does it do?

A. It's a relative new society. When, I guess, when the federal agencies began to come up with normal risk assessment calculations and when they began to think about how do we use this to make regulatory decisions, a group of people who were involved in this area, engineers, air pollution monitoring people, mathematical modelers who were into this said, "Gee, here's an area where maybe we can collect all of these people together so we can think a little more constructively how we can do this difficult job." Because it was becoming part of the fabric of the regulatory process of the country, and people had an uncertainty whether the way they were going was the right way. It was founded about 10 years ago and I was a member of the board for a couple of years.

Q. The Society of Toxicology.

A. It's got a very rigorous membership screening progress. The way I know, I have been a member of the membership committee for the past two

years. The basic move is to try to keep the quality of the society very high. Nomination. So membership is looked at very high by the membership committee.

Q. Finally on your resume you indicate you are a fellow in toxicology of the Academy in Toxicological Sciences.

A. Yes.

Q. What does that mean?

A. There is a group of maybe 100 or 120 of, I guess, the most senior and leading toxicologists in the country. And there is -- when I was first elected, there was a very large documentation that I had to send in about my publication experience, my experience in public bodies. And there is a board of governors there that elects these people to this academy.

Q. Do they have a publication?

A. No.

Q. Have you ever been a peer reviewer?

A. Oh, yes.

Q. For what publications?

A. I have been on the publications board for the journal Mutation Research, for the journal Cancer Letters, and for the journal Toxicology and Applied

Pharmacology. And I serve three or four years term as a reviewer and editor on each of those three journals. And I served ad hoc sometimes. People know I'm in certain areas so I will get a paper from someone I know who is an editor who says "Will you please review this because it's in your area." And that happens three or four times a year.

Q. Have you ever acted as a reviewer for any journal article relating to cigarette smoking and health?

A. I'm not sure. What do you mean by "cigarette smoking and health"?

Q. Cigarette smoking and adverse health consequences in human beings.

A. I don't think I ever reviewed a paper like that.

Q. Have you ever been a peer reviewer for any journal article relating to cigarette smoking and health with respect to epidemiological study?

A. No.

Q. Are you aware as to how the Surgeon General's reports are compiled?

A. Generally.

Q. What is your understanding?

A. My understanding is that several expert committees are brought together. Those expert committees review the documentation that is going to be done. And they prepare the actual written form, and that written form is then reviewed by another group of people prior to publication.

Q. Would you say it's a fairly rigorous process?

A. Yes.

Q. Would you say that the people who are participating in that process are experts in the field?

A. It's a very wide range of people, a large number of people. And I think their level of expertise ranges over a degree.

Q. Well, let's talk about the people who actually prepare the various chapters in the Surgeon General's Reports. Are you aware how that is done?

A. Yes.

Q. Would you say that those individuals are experts in their field?

A. In general, yes.

Q. Do you know any exceptions to that statement?

A. In the absence of exceptions -- not being an insider to the review process, and, again, having participated in areas like this where you have 15 people prepare things and 13 of them turn out to be okay and two don't turn out to be okay and you have to send them to somebody else to do that, this will never appear in the description of how the process was done.

Q. But would you agree, if somebody didn't make it as you described, they wouldn't be invited to do it the following year or thereafter, is that correct?

A. I think there is a reasonable probability of that.

Q. Have you ever been asked to participate in the preparation of any portion of the Surgeon General's Reports dealing with cigarette smoking and health?

A. No.

Q. Would you think the reason you might not have been asked to do that is you don't have specific expertise in that area?

A. No.

MR. KEARNEY: I object to the form of the question.

Q. Do you understand why you haven't been asked to do that?

A. No.

Q. Would you expect to be asked to participate in that process, for example, in the area of cigarette smoking and health disease again in the area of epidemiology?

A. No.

Q. Why would you not expect to be asked to do that?

A. I am not --

MR. SIRRIDGE: Object to the form of the question.

Q. You can answer it.

A. That is not the strongest area of my scientific background, and that is not the place where I can contribute the most.

Q. If I was to ask you, Dr. Sivak, what are you an expert in, what would you say?

A. My basic expertise is in the study of experimental carcinogenesis, the study of tumor promotion, the study of the mechanisms of how cancer might occur and how tumor promotion occurs in experimental systems, an understanding of how the

total body of evidence from all sources might relate to making judgments and decisions about hazards to humans.

MR. KEARNEY: Marc, based on our decision to end at 5:00 o'clock, I have made a commitment that I have to fulfill at 5:00.

MR. EDELL: Is this a logical point for me to stop?

MR. KEARNEY: Yes. Is there a more logical point in the next five minutes?

MR. EDELL: No.

(Time noted: 5:00 p.m.)

_____

Subscribed and sworn to before me this_____day of_____1991.

C E R T I F I C A T E

STATE OF NEW YORK)
: ss
COUNTY OF NEW YORK)

I, JOSE A. CENTENO, a Certified Shorthand Reporter and Notary Public within and for the State of New York, do hereby certify:

That ANDREW SIVAK, the witness whose deposition is hereinbefore set forth, was duly sworn by me and that such deposition is a true record of the testimony given by such witness.

I further certify that I am not related to any of the parties to this action by blood or marriage, and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 8 day of March 1991.

José A. Centeno

JOSE A. CENTENO, CSR

February 28, 1991

I N D E X

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